

# **The adherence to effective vaccine stock management protocols in the government facilities, the availability of vaccines, and the effectiveness of the stock visibility system in OR Tambo District of the Eastern Cape Province of South Africa**

**By**

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*Dissertation presented for the degree of Doctor of Philosophy in Public Health in the Faculty of Medicine and Health Sciences at Stellenbosch University*

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December 2019

## Declaration

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## General abstract

Effective vaccine stock management is one of the criteria for a functional vaccine supply chain. It ensures that the quality of vaccines is maintained and that vaccines are continuously available at service delivery points. The continuous availability of vaccines is a vital component of the health system which is required to achieve public health goals such as improved immunisation coverage, and universal health coverage.

Reports on vaccine availability and stock management of vaccines in OR Tambo district of the Eastern Cape Province are scarce. Also, since the implementation of the mobile device for stock reporting, stock visibility solution (SVS), no study has explored the experiences of the health care workers in order to identify potential barriers and facilitators to the implementation of the system. This study was therefore aimed at assessing the vaccine stock management status as well as availability of vaccines in the OR Tambo district, in Eastern Cape Province, South Africa.

As part of the literature review, we firstly gathered evidence on occurrence of vaccine stock - outs at different levels of the supply chain; the national, district, health facility level in the WHO African region. A systematic search of the literature was conducted to identify studies reporting on vaccine stock-outs at these levels. Furthermore, a cross-sectional study was conducted to assess the occurrence of vaccine stock-outs and vaccine stock management practices in primary health care settings in the Eastern Cape province, South Africa. Data was collected from a total of 64 PHC facilities using a researcher administered questionnaire, record checks and direct observation. This was followed by a qualitative study to explore the perceptions and experiences of the SVS system amongst healthcare workers (HCWs) who are involved with managing stock levels of medicines in primary health care facilities in the Eastern Cape Province. Consequently, a scoping review was conducted to summarise currently available information on interventions for vaccine stock management.

Quantitative data was managed using an electronic data capturing tool, REDCap, and descriptive statistics, and Pearson's chi-squared test, were conducted using STATA® Version 14. The qualitative data was analysed using thematic analysis.

Based on the JRF data, approximately 50% of the countries in Africa reported stock-outs of at least one vaccine for at least one month at national and district levels, in 2017. Fourteen (30%) countries reported vaccine stock-outs in 2017 at the national level. BCG vaccine is the most affected vaccine, with an increase from five countries in 2010 to 16 counties in 2015. There is an 86% chance of stock-out at the district level is caused by stock-out at the national level being linked to national level stock-outs and a 62% chance of this leading to interruption of immunisation services at the facility level. At the facility level stock-outs

reports from Africa were few. We found a total of eight studies that reported vaccine stock-outs across Africa; South Africa (5); Nigeria (1); Guinea (1) and Kenya (1) and Ethiopia (1). Poor stock management, disease outbreaks, poor supply chain structure, delays in deliveries and lack of trained health personnel are possible causes of facility level stock-outs.

Both stock cards and the stock visibility solution (SVS) device were used in all the facilities for vaccine stock management. However, the health care workers were reluctant to fill in the stock cards. Less than half of the facilities visited 27 (44%) filled their stock cards regularly. The ordering system was weak; as only about half 31(49%) of the respondents understood the concept of maximum and minimum stock levels, which are needed for proper quantification of needs. Delays in receiving supplies from the pharmaceutical depot were commonly reported by facilities, which could have contributed to stock-outs. Common reasons for delays from the depot include staff shortages at the pharmaceutical depot causing a backlog of orders, delay from the suppliers, procurement delays and possibly lack of proper communication between the depot and the facilities.

A total of 49 (77%) health facilities had at least one stockout for at least one vaccine on the day of the visit. Furthermore, BCG and OPV were the most commonly affected vaccines in 37 (58%) and 28 (44%) facilities, respectively. Within the last two years (between February 2017- February 2019), BCG and OPV had the most prolonged median duration of 167 and 103 days, respectively. PCV experienced the most prolonged duration of stock-outs amongst the newer vaccines with a median duration of stock-outs of 85 days.

Four studies met our inclusion criteria (three before-after studies and one randomised trial). Three studies were conducted in low- and middle-income countries, while one was conducted in Canada. All the studies had various limitations and were classified as having a high risk of bias. Study findings suggest that use of digital information systems to improve information and stock visibility, coupled with other interventions (such as training of health care workers on the use of innovative tools and redesign of the supply chain to tackle specific bottlenecks) have the potential to increase vaccine availability, reduce response times, and improve the quality of vaccine records. Although more of well-designed studies are needed to strengthen the evidence base.

The SVS system was well understood by most HCWs, as a system for reporting stock levels to managers. They also displayed high commitment to ensuring the systems works. However, some factors were identified as potential barriers for efficient usage of the system. This includes staff shortages and high staff turnover, lack of responses from the managers, the extra workload that comes with the system, amongst others. The HCWs made various

suggestions for how the system might be improved, most pertinently the need for more pharmacists and pharmacy assistants and for these cadres to be primarily in-charge of stock management and the use of the SVS.

The OR Tambo district of South Africa, just like in other countries, suffers from vaccine stock-outs especially BCG, and OPV. Similarly, the lack of proper stock management linked to the use of manual stock cards, long response time from the pharmaceutical depot and inadequate fridge capacity may be responsible for stock-outs in the primary health care facilities in OR Tambo district. Interventions for improving vaccine availability should be considered, especially those focused on the factors highlighted above.

### **Funding statement**

The research reported in this dissertation was supported by the South African Medical Research Council with funds received from the National Research Foundation of South Africa through its Competitive Programme for Rated Researchers. This work is based on research supported wholly by the National Research Foundation of South Africa (Grant Number: 106035).

## Dedication

To the Almighty God for grace throughout the journey. This work is also dedicated to my late father, Walter Iwu, whose life was an embodiment of sacrifice, hard work, excellence and love for education.

## Acknowledgement

I would like to thank my supervisor, Prof Charles Wiysonge for his guidance, support and mentorship throughout this journey. Thank you for accepting to be my supervisor.

To my co-supervisor, Prof Usuf Chikte, thank you for your encouragement and ensuring that I acquire the necessary skills to undertake this project.

I am grateful to Dr Ntombenhle Ngcobo, for being a collaborator on this project. Thank you for bringing your wealth of experience, for supporting me, for staying through to the end of this project.

I would like to thank Dr Edward Nicol, at the Burden of Disease Unit, South African Medical Research Council, Cape Town, for setting up and training me on the use of REDCap. It made data collection and management easy for me.

To colleagues at Cochrane South Africa, South African Medical Research Council, Cape Town; Dr Anelisa Jaca, Dr Alison Wiyeh, Dr Sara Cooper, Ms Lindi Mathebula, Ms Elizabeth Pienaar, Dr Evanson Sambala, and others too numerous to mention, I thank you for your support, assistance and encouragement.

I am sincerely grateful to my praying mother, Mrs Florence Walter Iwu, for your constant prayers and motherly support. You truly have a heart of gold. To my siblings, Lucky Ugochukwu, Ngozi Deby, Kelechi Vivian, Njideka Florence, and Dozie Declan, thank you for being a great support system.

To my husband, Dr Ishmael Jaja, thank you for being a loving husband and a great supporter of my dreams. Thank you for taking care of our daughter, Tamunokieibi Janelle, those times I was away.

I am grateful to the Eastern Cape Department of Health and the OR Tambo District for the permission to conduct this study.

This work is sponsored by the South African Medical Research Council and the National Research Foundation of South Africa (Grant Number: 106035).



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## CHAPTER ONE

### 1.0. Background

#### 1.1. Expanded Programme on Immunisation in South Africa

The Expanded Programme on Immunisation (EPI) has contributed immensely to the reduction of deaths in children due to infectious diseases and has made a substantial contribution to human development<sup>1-3</sup>. The EPI in South Africa (EPI-SA) became an entity in 1995 with the birth of democracy. Before this, there were only six antigens covered by vaccines in the national schedule then: diphtheria, tetanus, pertussis (DTP), measles, polio, and tuberculosis. Since then, significant milestones have been achieved. Examples include the elimination of polio, in which the last wild poliovirus case was in 1989; elimination of neonatal tetanus in 2002; and the introduction of new vaccines such as rotavirus vaccine and pneumococcal conjugate vaccine (PCV) in 2009 and human papillomavirus (HPV) vaccine in 2014.<sup>4</sup> The introduction of PCV in South Africa led to a dramatic decline of deaths caused by pneumococcal diseases in both children and adults<sup>5</sup>. In 2015, South Africa became the first country in Africa to replace the pentavalent vaccine, diphtheria, tetanus, acellular pertussis, inactivated polio vaccine and *Haemophilus influenzae* type B, (DTaP-IPV-Hib) with hexavalent vaccine; diphtheria, tetanus, acellular pertussis, inactivated polio vaccine and *Haemophilus influenzae* type B, hepatitis B vaccine (DTaP-IPV-Hib-HBV)<sup>6,7</sup>. The EPI-SA schedule as revised in December 2015 is shown in Table 1. Despite these achievements, the EPI-SA is faced with some challenges such as reported outbreaks of vaccine-preventable diseases, including measles and diphtheria outbreaks, in several parts of South Africa<sup>7</sup>, vaccine stock-outs and as well as concerns around immunisation coverage<sup>1,6,8,9</sup>.

Table 1: The current EPI schedule in South Africa

Age group	Vaccine	Mode/site of administration
Birth	Bacille Calmette Guerin (BCG)	Intradermal/Right arm
	Oral Polio Vaccine (OPV) (first dose)	Drops by mouth
6 weeks	OPV (first dose)	Drops by mouth
	Rotavirus Vaccine RV (first dose)	Liquid by mouth
	Diphtheria, Tetanus, acellular Pertussis, Inactivated Polio Vaccine, <i>Haemophilus influenzae</i> type b, and Hepatitis B, combined as (DTaP-IPV-Hib-HBV) (first dose)	Intramuscular /Left thigh
	Pneumococcal Conjugate Vaccine (PCV) (first dose)	Intramuscular/Right thigh
10 weeks	DTaP-IPV-Hib-HBV (second dose)	Intramuscular /Left thigh
14 weeks	DTaP-IPV-Hib-HBV (third dose)	Intramuscular /Left thigh
	PCV (second dose)	Intramuscular/Right thigh
	RV (second dose)	Liquid by mouth
6 months	Measles (first dose)	Subcutaneous/Left thigh
9 months	PCV (third dose)	Intramuscular/Right thigh
12 months	Measles (1)	Subcutaneous/Right arm
18 months	DTaP-IPV-Hib-HBV (fourth dose)	Intramuscular/Left arm
6 years (Boys and Girls)	Td vaccine (Tetanus and reduced strength of diphtheria)	Intramuscular/Left arm
12 years (Boys and Girls)	Td vaccine	Intramuscular/Left arm

Source: <https://www.westerncape.gov.za/service/immunisation> (accessed on 25 August 2019).

## 1.2. Vaccine supply chain

A functional vaccine supply chain is a critical element of an immunisation programme.<sup>10,11</sup> The current demands on the vaccine supply chain and other components of the EPI are much higher than the demands of the 1970s when the EPI programme was first designed. These include the increase in the number of available vaccines, storage requirements (due to the presentation of vaccines as single vials, as opposed to much earlier when multi dose vials used in the earlier days) that have significantly ballooned, and increased cost of vaccines. In fact, the number of doses of vaccines per individual has increased by six folds since 1974. It is projected that between 2011 and 2020 alone, the volume of vaccines will

increase by four folds; which will further increase the burden on immunisation services and more specifically on the vaccine supply chains<sup>11,12</sup>. Generally in this decade (2011-2020) many more countries have introduced newer and underutilised vaccines, coupled with other innovations. These developments further increase the burden of the already strained vaccine supply chain,<sup>13,14</sup> and resource-constrained countries are faced with the challenge of efficiently managing the current supply chain systems.<sup>15</sup>

The availability of vaccines in their right quantities is necessary to achieve targeted health goals.<sup>16</sup> Understanding the challenges and constraints of supply chain systems is essential for developing interventions to improve the performance of this system.<sup>16</sup> One of the most critical areas in the vaccine supply chain is ensuring consistent and continuous availability of quality vaccines.<sup>17</sup> When health facilities lack sufficient quantities of quality vaccines required for scheduled immunisation services, these sessions are cancelled leading to missed opportunities for vaccination, which will eventually reduce immunisation coverage<sup>17</sup>.

Health product supply chains, in general form the backbone of a health system. The availability of potent vaccines in the right quantities is necessary to achieve targeted health goals<sup>16</sup>. The requirements of an effective supply chain is much more than the: vehicles, containers, storage facilities. It involves a combination of the people, organisation, and other resources such as information systems all put together to ensure that health products move from their point of manufacture to the end user and the recipients at health facilities.<sup>16</sup> Weak vaccine supply chains reduce the public health impact of immunisation services as a result of a decrease in immunisation coverage caused by vaccine stock-outs; delay the introduction of new vaccines, increase vaccine wastage due to likely accidental exposure to extreme temperatures.<sup>18</sup>

Supply chain management involves overseeing the steps involved in moving a product from supplier to end-user.<sup>19</sup> Usually, when vaccines arrive in a country, they are stored in the central store, which is the national level store. Depending on some factors like the size of a country, or the number of health facilities, they are distributed to the regional or district level stores. From the regional stores, they are distributed to the health facilities. However, in some countries like Kenya, products could move directly from national stores to facilities.<sup>16,17</sup> While in the health facilities, they are stored until administered to recipients or sent further to secondary health facilities<sup>16,17</sup>. Distribution from the national level to lower levels vary from country to country. For some countries such as South Africa, Zambia and Tanzania, distribution from national level to lower level is every month while in others such as the Gambia, Kenya and Mozambique, it is every three months.<sup>16,20</sup> The lower levels could either be the health facilities or sites for outreaches.<sup>16,17</sup> The health facilities receive their vaccine

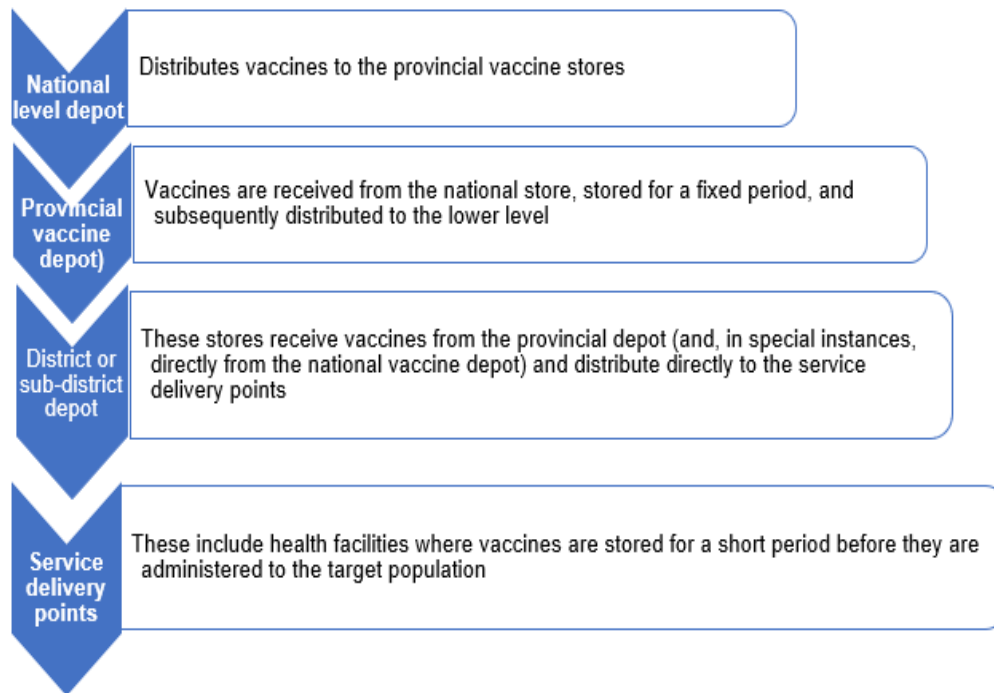


supplies through two types of systems, the push and pull system. The push system involves the higher level store such as the national store, district-level store or regional store deciding the number of products to be delivered to a health facility. This decision is made based on the target population, the incidence of disease and other factors. The push system may be used when the lower level in the supply chain cannot or is not able to or adequately manage its vaccine stock and place orders. On the other hand, the pull system operates from the level of the health facility, where by requisitions are made by the health facility based on their consumption, stock level and other factors<sup>16</sup>.

### **1.3. Overview of the vaccine supply chain in South Africa**

There are four levels of the vaccine supply chain in South Africa: national depot, provincial depot, district and sub-district depots, and service delivery points (as illustrated in Figure 1 below). Supply chain functions at the national level are outsourced to the Biovac Institute, that is in a public-private partnership with the South African national department of health (NDOH). According to the agreement, the Biovac institute manages three aspects of the vaccine supply chain: procurement of vaccines for the country, central level storage and distribution of vaccines from central level to the nine provincial storage depots.<sup>21</sup> The national department of health has the role of forecasting annual national vaccine requirements. When vaccines arrive the national depot, they are transported to provincial depots, from provincial depots they are transported to the district and or sub-district depots, and from these to health facilities where children and pregnant women (where appropriate) are vaccinated <sup>21,22</sup>.

This model of the vaccine supply chain in South Africa is outlined in the flow diagram below:



**Fig 1: Schematic diagram showing the distribution of vaccines in South Africa**

#### **1.4. Vaccine stock management**

The supply chain cycle for every health product is comprised of several components, namely: product selection, quantification, procurement, inventory/stock management, distribution, and ensuring rational use.<sup>23</sup> Each stage is important and is related to other stages, such that the problems encountered in any of these elements may have an impact on the entire supply chain system.<sup>23</sup> The success of immunisation programmes depends mostly on a well-functioning supply chain,<sup>24,25</sup> which ensures that vaccines are continuously available from the manufacturers through the different levels of the supply chain up to the target population.<sup>26</sup> Effective vaccine stock management is one of the criteria for a functional vaccine supply chain.<sup>27</sup> Effective vaccine stock management helps to: maintain the quality of vaccines<sup>27,28</sup>, prevent vaccine stock-outs and ensure continuous availability of vaccines to the target population. Vaccine stock management at health facility level involves activities that should be performed daily; including checking and monitoring of vaccines upon arrival at a storage point, during storage, and when they are administered to the recipients.<sup>27,28</sup> Physical stock counts should also be carried out regularly to validate stock records.<sup>27,28</sup>

The purpose of the vaccine stock management system in a supply chain is to ensure that vaccines are moved from the source to those who need them at the right time and in a cost efficient manner<sup>27</sup>. At the health facility level, this implies that vaccine stocks are expected to be kept in the right quantities at all times<sup>27</sup>. In order to ensure that the quality of vaccines is maintained, there is a need for accurate stock records. These vaccine stock records capture all the information on the vaccines, their diluents, and consumables such as syringes. This information includes arrival date; quantities of vaccines received, dispensed, and stock balances (quantities remaining); batch numbers; vaccine expiry dates; and the status of temperature monitoring indicators.<sup>20,27,26</sup> Ensuring consistent availability of sufficient quantities of vaccines depends on adequate the stock management processes that are consistently applied.<sup>20,27</sup> Stock management involves tracking the consumption rate of a product, and this helps the storekeeper to measure the future needs of the facility. Stock cards and stock books are common tools used to keep stock records<sup>29</sup>. These tools can be used to determine the average consumption rate for a defined period, minimum and maximum stock levels as well as timing the order of a particular product.<sup>29</sup> Vaccines are expected to be kept within the minimum and maximum stock levels. The minimum stock level is the least amount of vaccines that a facility should always have. It is expected that stocks should not drop below this level. To avoid stock-outs, it is expected that facilities maintain accurate minimum stock levels. It is also expected that physical counts of vaccine stocks be carried out regularly to verify stock records. Furthermore, facilities are expected to have a 'safety stock' which is that reserve stock that is used to prevent stock-outs that may arise due to unforeseen circumstances like delivery delays, shortages at supplier level, etc. This safety stock forms part of the minimum stock that a facility is expected to maintain. These stock levels usually depend on the consumption level of a facility<sup>20,27</sup>.

According to WHO, an ideal vaccine stock management system should:

- “Ensure that vaccines received are of assured quality by meeting the norms specified by the national regulatory authority or WHO;
- Ensure the availability of adequate quantities of relevant immunisation-related supplies (diluent, syringes and needles) to guarantee safe administration;
- Avoid stock-outs to ensure uninterrupted implementation of immunisation activities;
- Maintain proper handling and storage conditions to avoid overstocking and unnecessary expiration of materials before utilisation; Ensure adequate cold store capacity for vaccines at recommended storage temperatures and adequate dry store capacity for injection supplies”<sup>30</sup>.

### 1.5. Indicators commonly measured during the assessment of the stock management procedures

**Vaccine stock-out rates:** measures product absence over a period (12 months in this study). It is expressed as: (number of facilities that experienced a stockout of a specific vaccine/total number of facilities that are expected to provide that vaccine X 100. Data will be obtained from physical inventories, Logistics management and information systems (LMIS) records, stock cards/computer files or supervision records, where available.

**Inventory accuracy rates:** This indicator measures the accuracy of data on product stock levels at a facility and provides information on how accurately the facilities are tracking their inventories. It measures whether stock balances recorded on a stock ledger, stock cards or automated systems are similar to the actual inventory on hand. This indicator is important because the actual stock-on-hand is essential for forecasting and procurement purposes. Formula: (number of items where stock record count equals physical stock count / total number of items counted) X 100

**Stocked according to plan:** This measures the percentage of facilities with stock levels above the established maximum level for each vaccine at a specific point in time. It helps reveal overstocking or low stock levels. Formula: (number of facilities with stock levels between the established maximum or minimum levels/total number of facilities visited) X 100.

**Response time:** Also referred to as order lead time, the response time measures the average time it takes from when an order is placed from the facility to a higher facility (e.g. the district store) to when its order is received during a specified period (12months).

Formula for measurement of lead time: the sum of the number of days between when orders were placed and when orders were received/ total number of orders placed.

### 1.6. Approaches for addressing vaccine stock management issues.

Due to the upward trend in the rates of vaccine stock-outs, countries are currently using various approaches to manage vaccine stocks.<sup>31,32</sup> Such approaches include most commonly the use of digital technology in stock management. Using digital tools such as mobile devices in health care has the potential to strengthen health systems, in low and middle-income countries and improve global health<sup>33</sup>. This is possible due to the growing use information technologies in public health, a concept known as e health. The World Health Organisation (WHO) defines eHealth as “the use of information and communication technologies (ICTs) for health to, for example, treat patients, pursue research, educate students, track diseases and monitor public health”<sup>33,34</sup>. Mobile health is a component of e-

health, where mobile devices are used to assist public health activities and ultimately to improve health outcomes<sup>35</sup>. The Global Observatory for eHealth defined mHealth as “medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices”<sup>36</sup>. Mobile health has increasingly being adopted for several purpose in low and middle-ncome countries with great potentials<sup>37</sup>. It is currently being applied in various programmes such as maternal and child health, and programmes reducing the burden of the diseases, including HIV/AIDS, malaria, and tuberculosis <sup>36</sup> to improve timely access to health services and information, managing patient care, reducing drug shortages, improving clinical diagnosis and treatment adherence, among others<sup>36,38</sup>. A systematic review conducted by Oliver-Williams and colleagues showed that mhealth has the potential to increase vaccination uptake. In their study they described studies where mobile devices were used as reminders for health care givers and as a means of interactions between health care workers.<sup>39</sup> Mhealth also has the potential to improve the availability and quality of data in the health supply chain<sup>40</sup>. This is because data is needed to inform health managers on how the supply chain is functioning, understand where challenges are and make informed decisions. Lack of adequate data affects vaccine availability; because orders are not informed by consumption figures. Subsequently, ill-informed orders could lead to shortages and even wastage.

Vaccine stock management systems are typically still manual and mostly paper-based. Stock transactions are captured on paper, including vaccine stock (bin) cards and reports are sent to supervisors who make informed decisions based on the reports.<sup>41</sup> This, leads to inadequate information that is not able to support decision making due to various factors such as poor estimates, data arriving too late, poor data quality. Some countries use dashboards to visualize vaccine stock status. These dashboards measure performance and make them visible for managers to make informed decisions. Countries like India, Mozambique, and Nigeria use these dashboards to improve vaccine availability.<sup>42,43</sup>

South Africa developed the stock visibility solution (SVS), an mhealth system, to reduce the rate of stock-outs and improve the availability of essential drugs, which include vaccines. The SVS allows vaccine managers at higher levels in the supply chain to be better informed of the quantity of essential drugs at hand in health facilities. This should be helpful during distribution to avoid overstocking (which leads to vaccine wastages) or understocking (which leads to vaccine stock-outs).<sup>31</sup> The SVS involves the use of a mobile application designed to enable health facilities to monitor and capture stock levels daily. The information is stored in a cloud-based data management system and can send alerts when the stock is running low (Fig 2).<sup>44</sup>It enables health workers to replenish stock proactively.<sup>44</sup> The SVS is currently being used in 3126 clinics in eight out of the nine provinces in South Africa, except the

Western Cape Province.<sup>45</sup> The SVS was piloted in KwaZulu-Natal and Limpopo provinces in 2014 and 2015 respectively. There was a reduction in the number of stock-outs by 14% and 42% in Kwazulu-Natal and Limpopo respectively.<sup>45</sup> However, the method for measuring these variables was not mentioned. The use of the SVS approach looks promising. However, there has not been a significant reduction in the rate of stock-outs in many facilities in South Africa as of 2015, as there were still reports of stock outs.<sup>44</sup> The Stop Stock Outs Project (SSP) by a civil society organisation that conducts annual telephonic surveys to check on shortage of pharmaceuticals right through the country, still reports vaccine stock-outs<sup>44,46</sup>. However, the method used by SSP might require validation as there are reservations as to the validity of the method used for reporting <sup>45,47</sup>. Malawi has similar kind of mobile technology for capturing and monitoring vaccine stock level.<sup>48</sup>



**Figure 2: An illustration showing how the SVS works (Source: Mandimika 2016<sup>49</sup>)**

### **1.7. Vaccine shortages and stock-outs**

The incidence and duration of vaccine stock-outs are the most common indicators for measuring vaccine availability.<sup>50</sup> It is ideal for measuring stock-out rates at the lowest level of

the supply chain.<sup>50</sup> Following the resolution of the World Health Assembly to address global shortages of medicine and vaccines, a group of experts came up with definitions of stock-outs and shortages which are still subject to change. According to these experts, shortage occurs when “the supply of medicines, health products, and vaccines identified as essential by the health system is considered to be insufficient to meet public health and patient needs”, and stock-outs are defined as “the complete absence of the medicine, health product, or vaccine at the point of service delivery to the patient”.<sup>51,52</sup> Various studies that have assessed the supply of vaccines and other health commodities have used this definition.<sup>53–55</sup>

Many countries across all income groups have reported vaccine stock-outs<sup>51</sup>. For example, global data analysis of effective vaccine management (EVM) assessments between 2009 and 2014 showed that most countries performed below the minimum standard for stock management<sup>56</sup>. Vaccine stock-outs at primary healthcare facilities is one of the challenges facing the EPI in South Africa, and it is an undeniable threat to the success of the immunisation programme and the health of the people of South Africa.<sup>44,57</sup> Vaccine stock-outs tend to occur more at the primary health care facilities than at the supply levels above, i.e. the district and provincial depots.<sup>58</sup> In keeping with observations made elsewhere, vaccine shortages in South Africa seem to have increased since the introduction PCV, and rotavirus vaccine (RV), and the pentavalent vaccine.<sup>6</sup> The latter contains diphtheria, acellular pertussis, tetanus, *Haemophilus influenzae* type b, and inactivated poliovirus antigens. A national evaluation conducted in all provinces by the National Department of Health, the World Health Organisation (WHO), and the United Nations Children Fund (UNICEF) in South Africa after the pentavalent vaccine, PCV and RV were introduced, found that more than 60% of facilities visited experienced vaccine stock-outs in the 18 months period from December 2009 to July 2011.<sup>6</sup> Surveys conducted within the context of the “Stop Stock Out” project have reported similar findings. The “Stop Stock Out” surveys are mainly based on telephone interviews to identify facilities where stock-outs occur.<sup>44</sup> Vaccine stock-outs and child deaths due to vaccine-preventable diseases are common in rural communities which are remote and most have poor infrastructure and are hard to reach.<sup>59</sup>

Weak supply chains lead to weakness of the entire health system, putting the lives of patients in danger. Understanding the magnitude of a problem is one of the steps taken towards solving the problem. Also, identifying root causes of stock-outs is important for developing interventions that could solve these issues.<sup>16</sup> During the 69<sup>th</sup> World Health Assembly (WHO) in 2016, member states were advised to develop strategies that may be used to either forecast, avert or reduce the stock-outs of vaccines and other essential medicines. Such strategies should align with the priorities of each country such as the use of



notifications for predicting shortages, ensuring that standard procedures for procurement, distribution and contact management are adhered to; to develop and or strengthen systems that can be used to monitor supply, demand and availability of vaccines and other medicines, and be able to notify procurement departments when there are issues with availability amongst others.<sup>24</sup>

Chapter two of this dissertation will examine the magnitude of stock-outs at all levels of the supply chain in Africa, using a systematic review. Apart from highlighting the magnitude of vaccine stock-outs, this systematic review will assess the causative factors of vaccine stock-outs at the health facility level.

### **1.8. Study rationale**

While South Africa has made significant progress with the introduction and self-financing of new and underutilised vaccines<sup>1,6,9</sup>, vaccine shortages at the facility level seem to have been a challenge. There have been reports that point to significant shortages of vaccines in many parts of the country which have been more of a serious challenge since the introduction of new vaccines<sup>6,44</sup>. However, despite these reports, there is limited information on the actual shortages of vaccines and their impact; especially in certain parts of the country such as the Eastern Cape Province. Specifically, there is no literature on the level of availability and stock management of vaccines in OR Tambo district of the Eastern Cape Province, one of the most rural districts in the country. Finally, with the introduction of the SVS, it is important to understand the experiences of health care workers using the system, to understand their views regarding its effectiveness in reducing occurrence of stock-outs in primary health care facilities.

As a background to this study, a review of the availability of vaccines at different levels of the supply chain in the WHO Afro region, was conducted. This was followed by an assessment of vaccine stock availability and stock management practice in OR Tambo district. Subsequently, a scoping review was conducted to identify interventions that are used for vaccine stock management in primary health care facilities. Finally, we explored the perceptions and experiences of health care workers, using the SVS for monitoring and reporting of vaccine stock levels.

### **1.9. Summary of background and conceptual framework**

Access to vaccines is critical to achieving universal health coverage. It is also critical to achieving the strategic goals of the Global Vaccine Action Plan (GVAP), which includes improved immunisation coverage.<sup>11</sup> The supply chain involves a combination of the people,



organisation, resources, information; all working together to ensure that health products move from their point of manufacture up to the patients who receive them.<sup>16</sup> The vaccine stock management is a critical component of the vaccine supply chain, and poor stock management has been linked to the occurrence of vaccine stock-outs. At the health facilities, the major causative factor for stock-outs is poor stock management, especially when vaccines are available at the higher level of the supply chain.<sup>60,61</sup>

The conceptual framework used in this study was drawn from the WHO effective vaccine management (EVM) assessment and other areas the literature regarding the vaccine supply chain. The EVM is an initiative launched by WHO and UNICEF to help low- and middle-income countries upgrade their immunisation supply chains in order to manage present and future procedures. This initiative began by establishing a process to help developing countries evaluate the current performance of their supply chain and comparing it with the set standards. An EVM assessment tool was therefore created to achieve this purpose, to assess immunisation supply chain at all the relevant levels of the system, from the national to the service delivery levels. There are nine areas that are assessed by this tool: vaccine arrival, temperature control, storage capacity infrastructure, maintenance, stock management, distribution, vaccine management and information systems. At the health facility level, the vaccine arrival and information systems are not assessed. Eventually, EVM is expected to help countries ensure that lifesaving vaccines are available, are in good quality when they reach service delivery levels and improve efficiency of every country's vaccine supply chain.<sup>62</sup> The conceptual framework below illustrates the interplay between factors that cause vaccine stock-outs at the health facilities, with a focus on vaccine stock management.

Figure 2 below describes the conceptual framework developed for this study to aid in data collection

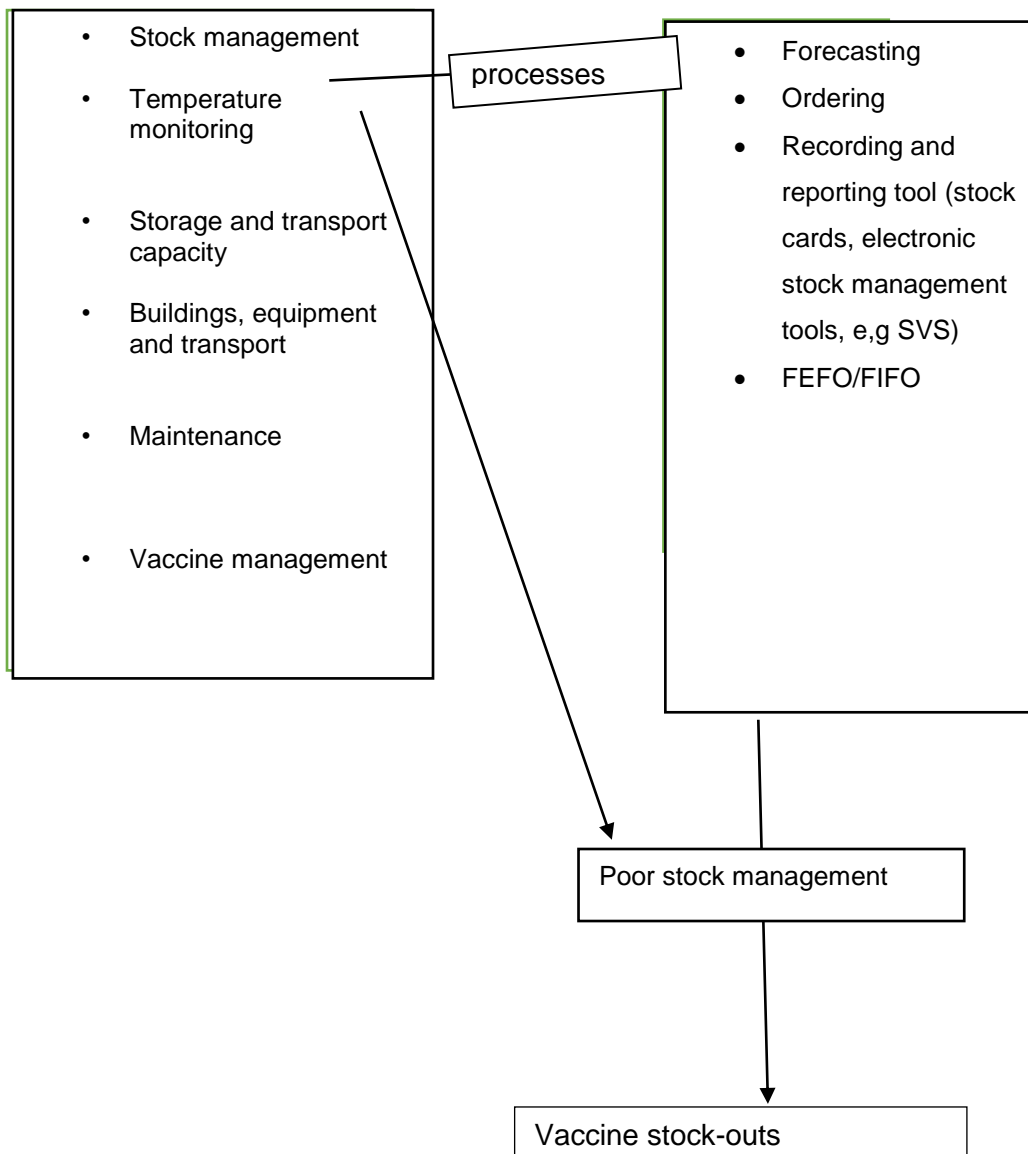
**Vaccine arrival at port of entry (National level)**



**Sub-national level (provincial and/or district level)**



**Health facility**



**Figure 3: The conceptual framework showing factors that influence vaccine stock management and stock-outs**

### **1.10. Aim of the study**

This study aims to evaluate vaccine stock management status of primary healthcare facilities and the availability of vaccines in the Eastern Cape Province of South Africa.

### **1.11. Specific objectives of the study**

- i. To conduct a systematic review of both published and grey literature on occurrence vaccine stock-outs in WHO African region in the decade of vaccines.
- ii. To assess the standard of vaccine stock management in selected primary healthcare facilities in the Eastern Cape Province of South Africa.
- iii. To establish the level and frequency of vaccine stock-outs in selected primary healthcare facilities in the Eastern Cape Province of South Africa.
- iv. To conduct a scoping review of the approaches for vaccine stock management, to reduce stock-outs in primary healthcare settings.
- v. To explore the perceptions and experiences of health care workers using the stock visibility solution (SVS), in the Eastern Cape Province of South Africa.

### **1.12. Structure of the dissertation**

This dissertation is structured into six chapters, mainly written in manuscript format. Chapter 1 provides a background to the study. Here we discuss the benefits of immunisation through the EPI, including the achievements and successes of the EPI in South Africa. This chapter also describes the vaccine supply chain and how important it is in achieving health goals, particularly immunisation goals. Furthermore, the concept of vaccine stock management is discussed and how it impacts on vaccine availability. This is then followed by a description of vaccine stock-outs and its impact on the health system.

Chapter 2: To build upon the concepts of vaccine stock-outs, Chapter 2 describes the occurrence of vaccine stock-outs in the WHO African region, including the national level, district and health facility level. It also describes the link between national level stock-out and district stock-out and the impact on immunisation services. The causes of vaccine stock-outs at the health facility level is also highlighted in this chapter. A systematic review of both published and grey literature on the occurrence of stock-outs was conducted. Also, the WHO/UNICEF joint reporting form is used as a data source for national and district level vaccine stock-outs.

Chapter 3: This chapter shows the findings of the primary study conducted in the Eastern Cape province of South Africa. That is, findings from the assessment of vaccine stock-outs and stock management in primary health care facilities, in OR Tambo District, Eastern Cape.

Chapter 4: From findings from Chapter 3, we found that stock-management issues are the most frequent causes of vaccine stock-outs at service delivery points. So, we decided to conduct another scoping review of the literature to identify interventions that can be used to improve vaccine stock management and vaccine availability. This study has been published in *Human vaccines and immunotherapeutics* (<https://www.ncbi.nlm.nih.gov/pubmed/31116638>)

Chapter 5: Chapter dealt with a qualitative study on the perceptions and experiences of health care workers on the use of SVS.

Chapter 6: This chapter is a general discussion and conclusion. It also describes a summary of key findings, benefits of the study, contribution to knowledge, study limitations and future research considerations.

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## CHAPTER TWO

### A systematic review of vaccine availability at the national, district, and health facility level in the WHO African Region.

This manuscript has been submitted to *Expert Reviews of Vaccines*.

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## **2.0. Abstract**

### **Introduction**

Despite the many benefits of immunisation, the WHO African region is still faced with challenges, in terms of vaccine availability. In this study, we describe the occurrence of vaccine stock-outs at the different levels of the supply chain; national, district and health facility level in the WHO African region. We conducted a systematic review to search to identify studies reporting on vaccine stock-outs at these levels.

### **Methods:**

We searched both published and grey literature to identify studies that reported on vaccine shortages and stock-outs at national, district levels and health facilities, in the decade of vaccine (between 2010 and 2017). The following databases were searched; PubMed, Embase, Cochrane Central Register of Controlled Trials (CENTRAL). Also, we searched the following websites for grey literature; WHO/UNICEF Joint Reporting Form (JRF), TechNet21, UNICEF, GAVI, PATH, and the reference sections of eligible studies.

Data for national and district stock-outs were extracted from 2018 WHO/UNICEF JRF, that reports on 2017 data. We focused on BCG, DTP, Measles and OPV. Data were captured in Microsoft excel and analysed using descriptive statistics.

### **Results:**

Based on the JRF data, approximately half of the countries in Africa reported stock-outs of at least one vaccine for at least one month at national and district levels, in 2017. Fourteen (30%) countries reported vaccine stock-outs in 2017 at the national level. BCG vaccine is the most affected vaccine, with an increase from five countries in 2010 to 16 counties in 2015. There is an 86% likelihood of stock-out at the district level is caused by stock-out at the national level being linked to national level stock-outs and a 62% likelihood of this leading to interruption of immunisation services at the facility level. At the facility level, stock-outs are underreported but still occur. We found a total of eight studies that reported vaccine stock-outs across Africa; South Africa (5); Nigeria (1); Guinea (1) and Kenya and Ethiopia (1). Poor stock management, disease outbreaks, poor supply chain structure, delays in deliveries and lack of trained health personnel are possible causes of facility-level stock-outs.

**Conclusion:** Countries within the WHO African region still report stockouts at all the levels in the supply chain and this impacts on the delivery of immunisation services. The frequency and the proportion of subnational levels that experience stock-outs vary between countries

and between regions within a country. Countries need to put more efforts towards finding lasting solutions to vaccine shortages.

**Keywords:** Vaccine stock-outs, shortages, immunisation, Supply chain, availability, Africa

## 2.1. Introduction

Gains of the Expanded Programme on Immunisation (EPI) in Africa have been significant. The EPI program has led to a reduction in the burden of vaccine-preventable diseases, with diseases such as polio and neonatal tetanus being close to elimination.<sup>1–3</sup> There is equally evidence from return on investment (ROI) studies in low-and middle-income countries demonstrating that about the cost of the illness averted, immunisation provides a net return 16 times more than what it costs to vaccinate. Expanded estimates in this study, which incorporated the value people place on living longer found that the return on investment can be up to 44 times the initial cost<sup>4</sup>. In order to optimise the benefit of vaccines, there has been accelerated progression in the introduction of new and underutilised vaccines such as Hepatitis B, rotavirus and pneumococcal conjugate vaccines. In thirty-six (36) out of the 47 countries in the region, this has been supported by the GAVI alliance<sup>5</sup>.

The Global Vaccine Action Plan (GVAP) is a framework that was adopted by the World Health Assembly in 2012 to achieve the vision of the decade of vaccines (2011 – 2020) by delivering universal access to immunisation. The goal of this plan is that by 2020, countries would have achieved 90% national immunisation coverage.<sup>6,7</sup> The vision of the decade of vaccine is to ensure everyone eligible for vaccination gets equal access to vaccines regardless of their location or income status (“where they are born, where they live and who they are”).<sup>6,7</sup> One of the strategic objectives of the GVAP and the African region is to have strong immunisation supply systems that will ensure that vaccines are always available in adequate quantities and improve immunisation coverage, respectively.<sup>8,9</sup>

As countries endeavour to increase their immunisation coverage and get closer to achieving universal access to life-saving vaccines as outlined in the GVAP, challenges abound. In 2017, about 20 million children were not vaccinated. Sixty per cent of these children come from 10 countries; with half of these countries in Africa, including Nigeria, Ethiopia, Democratic Republic of Congo, Angola and South Africa<sup>10</sup>. Immunisation coverage in low-and middle-income countries (LMICs) is low, stagnant, and even decreasing for some countries. In the African region, immunisation coverage with the third dose of diphtheria-tetanus-pertussis (DPT3) in the period 2010 and 2017, remained stagnant at 72%, while there was a 14% increase in birth cohort in the same period.<sup>2</sup>

Supply chains are fundamental to a functional immunisation programme and ensuring that vaccines are always available at the point of care. Efficient supply chains will ensure an uninterrupted supply of vaccines at all levels, and this is an essential factor in achieving and

sustaining high immunisation coverage levels.<sup>11,12</sup> Vaccine shortages result in targeted recipients being turned away, which lead to a decrease in immunisation coverage and ultimately outbreaks of vaccine-preventable diseases.<sup>13</sup> Additionally, it is evident that repeated shortages will lead to a decrease in demand for immunisation services, dent the image of the programme and further undermine national and global efforts on disease control.<sup>12</sup>

Furthermore, a study by Lydon et al.<sup>14</sup> examined global levels of vaccine shortages found that one in three countries are out of stock of at least one vaccine every year and the shortages were much more common in Sub-Saharan Africa, with 38% of countries reporting national level stock-out. Of further concern from this study is that, when national stock-outs occur, there is 89% likelihood of district level stock-out, resulting in 96% chance of interruption of services at facility level (Figure 3). The global shortage of BCG has been well documented and has led to estimates of its potential impact. The Western Cape province in South Africa, for example, has recorded a sharp increase in the incidence of tuberculous meningitis and this has been attributed to BCG vaccine shortages.<sup>15</sup>

Causes of vaccine shortages are many, and shortages may occur at any level in the supply chain. Of serious concern is shortages that occur at the district level and even more frequently at the facility level. Vaccine shortages and stock-outs that occur at district and facility levels when there is no national shortage, are mainly due to poor stock management and these are quite significant<sup>16</sup>. They are likely to go on for long periods unreported, undetected and may have a greater impact on immunisation coverage.

It is against this backdrop that we assess the magnitude of vaccine stock-outs at all levels, in the WHO African region since the beginning of the decade of vaccines. This study aims to determine the occurrence of vaccine stock-outs, the duration of stock-outs at both national, district and facility levels as well as the impact on immunisation services.

## **2.2. Methods**

### **2.2.1. Identification of vaccine stock-outs reported at the national and district levels in Africa**

#### **Data source:**

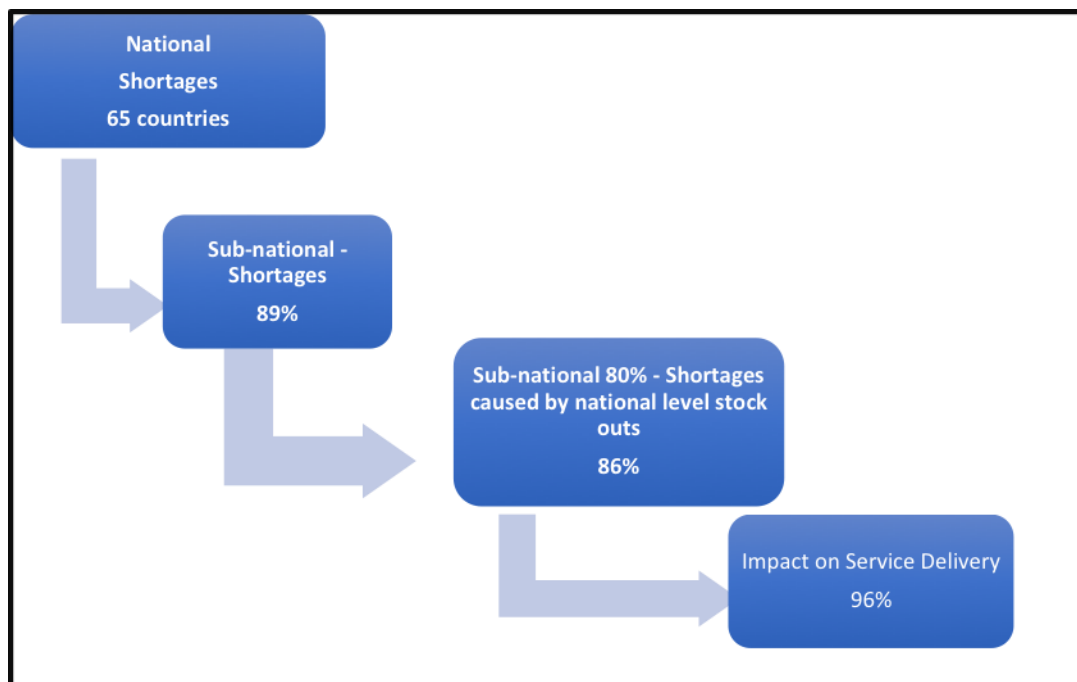
Data based on the WHO Joint Reporting Form (JRF) was used. WHO and the United Nations Children's Fund (UNICEF) collect data annually on the performance of the immunisation programmes from all WHO member states using the JRF. This data collection has been ongoing since 1998 and is available to the public. We retrieved the data from the

vaccine supply category of the JRF on the 3rd of December 2018, after it had been updated on the 28th of October 2018 [16]. This category has five main questions, namely:

- “Is there a stock-out at the national level” for BCG, (and other vaccines)?
- “If yes, specify the duration in months.”
- “Is there a stock-out in any district for BCG, (and other vaccines)?
- “Was the district level stockout linked to a national one for any of the vaccines?”
- “Vaccination services interrupted because of lack of the vaccines?”

Each question in this category for JRF is answered by countries with a yes (Y); no (N); not applicable (NA) or not reported (NR). Data was captured for only the “yes” responses for each vaccine and each year from 2010 to 2017. For quality checks, results were adjusted for any country that reported the duration of stock-outs but failed to report “Yes” to the question on stock-outs. If such countries failed to report yes for the national level stock out, we had to adjust the result to become “Yes” for that country since there is a high likelihood that there was a mistake in reporting.





**Figure 3: The link between the occurrence of national-level stock-outs and district level stock-outs and their implication of delivery of immunisation services, at a global level** <sup>14</sup>

**Inclusion criteria and considerations for analysis of vaccine stock-outs from the WHO/UNICEF Joint Reporting Form:**

The study was limited to countries in the WHO African region. We included only vaccines that are common in the immunisation schedules of children between 0 – 12 months of age, for all countries in the WHO African region. We focused on stock-outs of vaccines for the period from 2010 to 2017, with 2011 serving as the baseline. We included: BCG, diphtheria-tetanus-pertussis (DTP) containing vaccines, measles, oral polio vaccine (OPV) and pneumococcal conjugate vaccine (PCV). Since these vaccines are the most commonly used in the countries within this region. Other vaccines such as yellow fever, meningococcal type A conjugate vaccine (Men A), human papillomavirus (HPV), rotavirus, and tetanus toxoid were excluded from the analysis.

The following indicators were measured:

- i. The number of countries reporting national level stock-outs for each vaccine between 2010 and 2017. This was calculated from the countries that responded yes to the question on “was there a national level stock-out?”.
- ii. The number of countries reporting stock-out of at least one vaccine for at least one month or each year, between 2010 and 2017.

- iii. The average duration of stock-outs at the national level stock-outs for each vaccine, between 2010 and 2017
- iv. The number of countries reporting stock-outs at the district level for the individual vaccines for each year. This was obtained by calculating the total number of countries that answered a “yes” to the question “Is there a stock-out at the district level for BCG, DTP, Measles and OPV
- v. Number of countries with stock-outs at the district level that were due to the national level stock-outs, for each vaccine and each of the years under study.
- vi. The number of countries with vaccination services interrupted due to stock-outs at the district level.

Apart from measuring the average duration of stock-outs for each year, the duration of stock-outs based on the number of stock-out events was also described. This expression attempts to provide a broader picture of the duration of stock-outs at the national level. A stock-out event is defined as stock-out lasting for a minimum of one month [17]. As a standard, countries are expected to have a safety stock that will last for three months, so stock-out of up to a month implies that this safety stock has been depleted and this will most likely affect the lower levels [13].

### **Analysis:**

Data on national and district stock-outs were captured and analysed using descriptive statistics.

### **2.2.2. Identification of vaccine stock-outs reported at health facility level in Africa**

The JRF does not contain reports of facility-level stock-outs. Hence, we searched the literature for such studies. The following steps describe the methods used to systematically review the literature for facility-level stock-outs reported in the WHO African region.

### **Identification of studies and search strategy:**

We considered studies that have reported vaccine stock-outs at primary health care facilities level in Africa, irrespective of duration, vaccine type or study design.

### **Outcome measures:**

Primary outcomes:

- Stock-out rate: “the percentage of facilities (e.g., service delivery points [SDP], warehouses) that experienced a stockout of a specific product that the site is

expected to provide, at any point, within a defined period (e.g., the past six or 12 months)” or as defined by the authors.

- The average duration of stock-outs

The secondary outcome was the causes of vaccine stock-outs highlighted by the authors.

### **Search strategy:**

We searched both published and grey literature for studies that reported stock-out events in health facilities across Africa, in the decade of vaccine (between 2010 and date). The following databases were searched; PubMed, Embase, Cochrane Central Register of Controlled Trials (CENTRAL). We also searched the following websites for grey literature; WHO, TechNet21, UNICEF, GAVI, Program for Appropriate Technologies in Health (PATH), The reference lists of eligible studies were also searched. Appendix 1 contains search strategy used to search for eligible studies.

### **Selection of studies and data extraction:**

Two review authors independently screened through the titles and abstracts of the records retrieved from databases to identify potentially eligible studies. Studies reporting the absence of at least one vaccine in a primary health care facility were included in the study. A data collection form was designed and used independently by two review authors to extract data from the included studies. Where there was any form of disagreements, we resolved them through discussion and contacted a third review author in instances where the two authors had disagreements.

### **Synthesis of data from facility level stock-outs in the WHO African region**

The occurrence of vaccine stockouts reported in each included study was not homogenous. Therefore, it was impossible to calculate an overall stock-out from all the studies. Hence, results from the included studies were synthesised narratively.

## **2.3. Results**

### **2.3.1. Results from the WHO/UNICEF JRF on national and district stock-outs reports for the WHO African region**

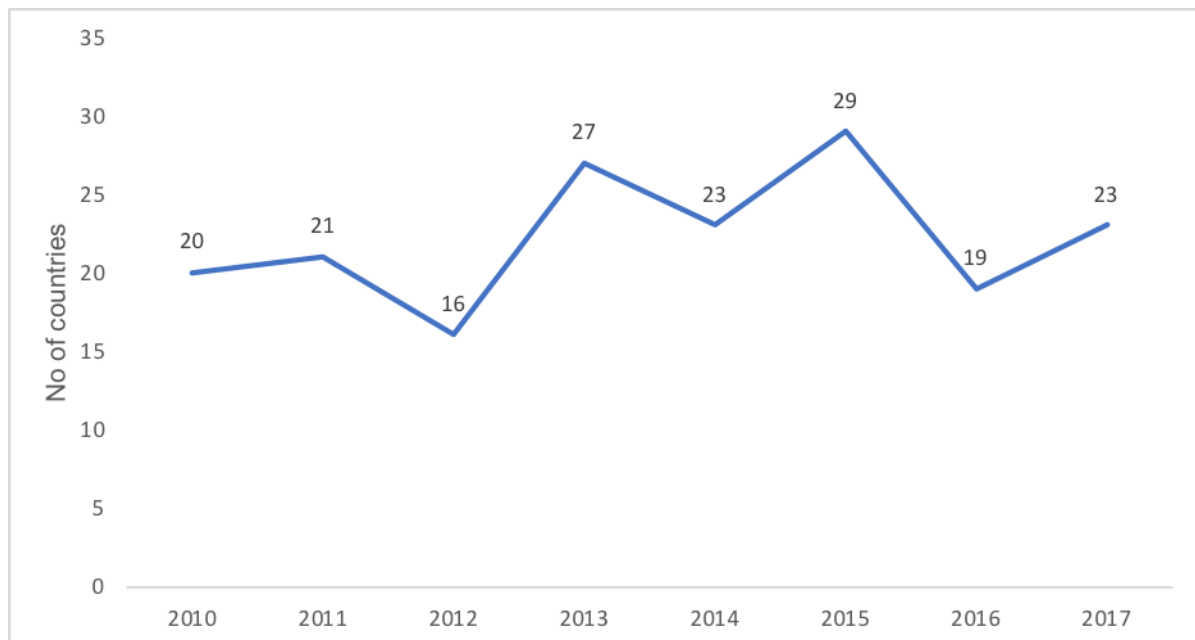
Five vaccines were included in the analysis; BCG, DTP containing vaccine (DTP, Measles, oral poliovirus vaccine (OPV) and PCV. The results described below are based on these vaccines. Data from all the 47 countries in the WHO African region was obtained.

### **National level stock-outs**

Between 2011 and 2017, there was much variation in the rates of vaccine stock-outs at the national level. In 2017, 49% (23/47) of all countries in the WHO African region reported a

stock-out of at least one vaccine for at least one month. This was lower than that of 2015, with 62% (29/47) of the countries reporting national-level stock-outs. The year 2015 had the highest number of countries reporting stock-outs at the national level.

There was an increase in the number of countries reporting BCG stock-outs at the national level since 2010. In 2010, five countries (11%) reported BCG stock-outs. This increased to 12 (26%) in 2017, with peaks of 13 countries (28%) in 2013 and 16 (34%) in 2015. There was a significant decrease in the number of countries that reported stock-outs of DTP containing vaccines, from 11 countries (23%) in 2010 to 1 in the country (2%) in 2017. Despite variations in the number of countries reporting stock-outs between 2012 and 2015, a steady reduction was observed from 2015 to 2017. Figure 4 shows a graph of the total number of countries reporting stock-outs between 2010 and 2017.



**Figure 4: Total number of countries reporting national level stock-outs in the WHO African region (2010-2017)**

There was no significant change in the number of countries reporting national level stock-outs of measles vaccine during the study period. Four countries (9%) reported stock-outs both in 2010 and 2017. There were minor variations between 2010 and 2017 in the number of countries reporting measles stock-outs. Oral polio vaccine (OPV) had no stock-out reports available from 2010 to 2013; only reports from 2014 – 2017 were available. From the reports, there was an increase in the number of countries reporting stock-outs of OPV from six countries (13%) in 2014 to seventeen countries in 2017. Table 1 below shows the

countries reporting national level stock-outs of BCG, DTP containing vaccines, Measles, OPV and PCV.

**Duration of national-level stock-outs**

The duration of stock-outs varied among countries and vaccines, ranging from one month (one stock-out event) to seven months (seven stock-out events). The vaccine most commonly affected was BCG. In 2016 and 2017, the duration of stock-outs reduced significantly. The duration of stock-outs for DTP containing vaccines in most countries was between zero to three months. Most countries in a year experienced multiple stock-out events of vaccines. In 2017, 15% (7/47) reported two stock-out events (lasting a month or more) and another 15% had three stock-out events (Table 3).

*The link between district-level stock-outs and the impact on immunisation services*

This indicator was added to the JRF in 2014, hence only results from 2014 to 2017 were reported (Table 2 below). In 2015, 25 countries out of the 29 that reported stock-outs at the national level reported that district-level stock-outs were due to national stock-outs. This suggests that there is an 86% chance of having a district-level stock-out being caused by stock-outs at the national level. In the same year, 18 countries out of 29 (62%), reported that there was an interruption of immunisation services.

**Table 1: Occurrence and duration of vaccine stock-outs at the national level in WHO African countries between 2010-2017**

Countries reporting vaccine stock-outs of each vaccine at national level n (%)								
	2010	2011	2012	2013	2014	2015	2016	2017
BCG	5 (11%)	6 (13%)	7 (15%)	13 (28%)	10 (21%)	16 (34%)	9 (19%)	12 (26%)
DTP	11 (23%)	8 (17%)	4 (9%)	7 (15%)	2 (4%)	6 (13%)	3 (6%)	1 (2%)
Measles	4 (9%)	7 (15%)	5 (11%)	7 (15%)	5 (11%)	3 (6%)	4 (9%)	4 (9%)
OPV	Not reported	Not reported	Not reported	Not reported	6 (13%)	4 (9%)	12 (26%)	17 (36%)
PCV	2 (4%)	1 (2%)	2 (4%)	1 (2%)	0 (0%)	1 (2%)	1 (2%)	0 (0%)
Duration of vaccine stock-outs at the national level n (%)								
One month	10 (21%)	11(23%)	12 (26%)	13 (28%)	6 (13%)	8 (17%)	9 (19%)	7 (15%)
Two months	4 (9%)	2 (4%)	2 (4%)	5 (11%)	5 (11%)	9 (19%)	6 (13%)	6 (13%)
Three months	4 (9%)	2 (4%)	2 (4%)	4 (9%)	2 (4%)	4 (9%)	1 (2%)	7 (15%)
Four months	2 (4%)	2 (4%)	1 (2%)	1 (2%)	5 (11%)	5 (11%)	2(4%)	2 (4%)
Average duration of stock outs (days) at the national level								
	72	43	45	57	81	66	50	69

**Table 2: Countries reporting district stock-outs and impact of higher-level stock-outs on immunisation delivery services**

	2014	2015	2016	2017
Number of countries that reported district level stock-outs	31	40	32	29
District stock-outs caused by National stock-outs	20	25	16	18
Interruption of vaccination services because of lack of vaccines	23	18	14	26

### 2.3.2. Occurrence of vaccine stock-outs at the facility level, within the WHO African Region

#### Search results

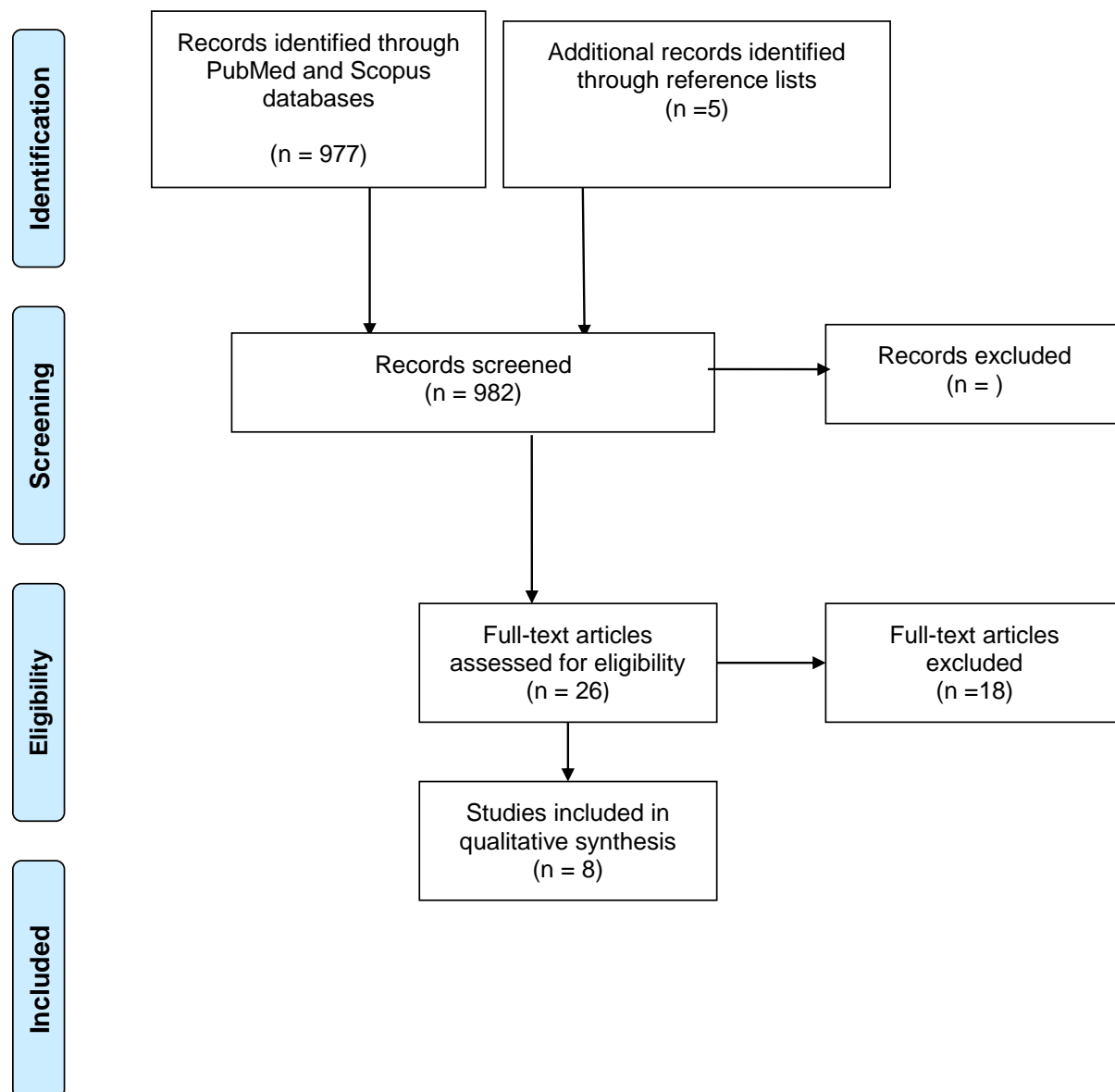
The literature search yielded a total of 982 records; 11 from PubMed, 966 from Scopus, and one from reference lists of included studies. After screening, 26 articles were retrieved for full-text screening, out of which eight articles were eligible for inclusion.<sup>17–24</sup> Eighteen articles were excluded. Figure 5 shows the PRISMA (Preferred reporting items for systematic reviews and meta-analyses) flow diagram of how studies were selected.<sup>25</sup>

#### Study characteristics

The first study was a cross-sectional study conducted by Ngcobo et al.<sup>17</sup>, in 2013, in a rural district of one of the Provinces of South Africa<sup>17</sup>. The occurrence of vaccine stock-out was assessed in 31 primary health care facilities. Vaccine stock-outs occurred in 29% (9/31) of the facilities visited. The duration of vaccine stock-outs in these facilities varied between less than two days to over two weeks. The following reasons were reported to be causes of vaccine stock-outs: poor stock management, lack of trained personnel, delays in vaccine deliveries due to stock-outs at district store, stock-outs at the Provincial store, and lack of vehicles to transport vaccines to the facilities.

The second study was conducted by Camara et al.<sup>18</sup> in 17 health facilities in a rural district of Guinea, between March 2013 to 28<sup>th</sup> February 2014. This study described the occurrence of vaccine stock-outs at three-time points; before, during and after the Ebola outbreak. Vaccine stock-outs occurred in all the 17 facilities before and during the Ebola outbreak but reduced significantly to only two facilities after the outbreak. During the pre-Ebola period, vaccines affected were BCG, polio, pentavalent and yellow fever vaccines. Together, these vaccines contributed to a total of 2760 days of stock-outs. Out of these days, the BCG vaccine was the most affected, with 2121 (77%) days of the entire duration of stock-outs. During the Ebola outbreak, the total duration of stock-outs was slightly lower than the pre-Ebola period, with a total duration of 2706 days. During this period, BCG and Polio vaccines were most affected contributing to 1452 (54%) days and 916 (34%) days of the total duration of stock-outs. During the post-Ebola phase, only two facilities experienced stock-outs and a 99% reduction in the duration of stock-outs to 18 days. According to the authors, vaccine stock-outs experienced before the Ebola outbreak may have been caused by a lack of stock cards used to record and monitor stock levels of vaccines.<sup>18</sup>





**Figure 5: PRISMA flow diagram showing the process of study selection**

The third study by Eboreime et al. 2015,<sup>19</sup> conducted in Nigeria in 2013, reported stock-outs of the oral polio vaccine (OPV) and pentavalent vaccine from four provinces, in Nigeria. A total of 1954 health facilities were assessed in two provinces each from the Southern and Northern regions of the country. From two provinces in the southern region, stock-outs occurred in 2.5%

(13/525) of facilities and 15% (95/622) facilities respectively. In the Northern region, stock-outs occurred in 1% (4/343) facilities and 2.4% (11/464) of facilities respectively.

The fourth study reported stock-outs that occurred in two countries after vaccine introductions. Stock-outs of the newly introduced vaccines occurred in 51% of facilities in Kenya and 8% in Ethiopia <sup>20</sup>.

We further included stock-out reports of national surveys of vaccine stock-outs in primary health facilities in South Africa. The survey is usually conducted telephonically by an independent consortium of civil society organisations, under a project called Stop Stock Out Project (SSP). These surveys were conducted in 2013, 2014, 2015 and 2017.<sup>21-24</sup> In 2013, 301 out of 2047 (14.7%) of facilities that responded to the survey, reported stock-outs of at least one vaccine in the entire country's immunisation schedule. The stock-out reports across each of the nine provinces were reported for years between 2013-2015 <sup>21-23</sup> (Table 3 below). The 2017 survey did not contain provincial summaries. From the provincial reports, disparities occurred between provinces; in 2014, the pentavalent stock-outs were most frequently reported in Limpopo with 28% (67/238) affected, while stock-outs of rotavirus vaccine was most reported in Eastern Cape where 10% (42/428) of facilities were affected. In 2015, 14% of facilities in the Eastern Cape experienced stock-outs of vaccines as compared to 7% in Free State (Table 3 below).<sup>23</sup> Between 2014 and 2017 the stock-out reports were based on three vaccines; rotavirus, DTP and measles. Within these years, there was a reduction in the proportion of facilities reporting stock-outs of these vaccines. For example, for the DTP vaccine (pentavalent or hexavalent), the proportion of facilities reported stock-outs reduced from 10% in 2014 to 4% in 2017 (Table 4 below).<sup>23,24</sup>

**Table 3: The proportion of facilities reporting vaccine stock outs across the nine provinces in South Africa, between 2013 – 2015<sup>21–23</sup>**

Province	2013 survey	2014 survey	2015 survey
Limpopo	35.6%	31% (73/238)	13% (32/248)
Free State	32.2%	7% (9/138)	7% (10/135)
Mpumalanga	15.5%	10% (7/173)	8% (18/220)
Eastern Cape	12.5%	15% (64/426)	14% (64/469)
Northern Cape	11.7%	8% (7/92)	7% (9/123)
North West	9.9%	13% (26/201)	17% (37/223)
Western Cape	9.5%	2% (4/245)	4% (13/326)
Gauteng	8.5%	4% (11/252)	11% (31/277)
KwazuluNatal	6.2%	10% (38/392)	14% (60/443)

**Table 4: Percentage of facilities reporting a vaccine stock out between 2014 and 2015 in South Africa<sup>#</sup>**

	2014	2015	2017
Rotavirus	6% (122/2194)	4% (91/2421)	4% (42/1078)
DTP*	10% (219/2194)	9% (209/2428)	4% (46/1074)
Measles	4% (78/2198)	3% (69/2425)	2% (24/1073)

<sup>#</sup> 2016 report was not available

\* Pentavalent in 2014 and hexavalent vaccines in 2015 &amp; 2017

## 2.4. Discussion

One of the strategic goals of the WHO African region is to improve immunisation coverage. However, this goal will not be reached if vaccine shortages continue to occur and cause disruption of immunisation services at the service delivery level. Countries need an uninterrupted supply of vaccines at different levels in the supply chain, especially at the lowest level, if they are to reach the coverage targets set for their immunisation programmes <sup>26</sup>. This review is important because identifying the magnitude and factors associated with vaccine stock-outs will enable policymakers to direct their efforts towards improving access and availability of vaccines at different levels of the supply chain

### 2.4.1. The occurrence of stock-outs at the national and district level and its implications to immunisation services

By 2020, it is expected that countries reporting on national level stock-outs will decline by 67%.<sup>27</sup> From the results obtained, it is evident that progress in the WHO African region is not on track to achieve this target. When shortage of vaccines occurs at the national level, this often results in shortages of vaccines at the lower levels, <sup>27</sup> which consequently lead to interruptions in immunisation activities at service delivery level. Eventually, countries will fail to reach their set target for immunisation coverage, increasing the risk of pockets of disease outbreaks in the population <sup>7,17</sup>. Depending on the duration, shortages of vaccines at the national level may not necessarily cause shortages at the district level or lead to interruption of immunisation services at service delivery points. Conversely, shortages at the district level can occur without shortages at the national level.

It is also important to note that, the reports on stock-outs through the JRF are likely to underestimate the actual incidence of vaccine shortages at the district level and more especially at the facility level. This could be because the country managers reporting on the JRF may not have received reports from lower levels on stock-outs since many shortages at service delivery level are not reported. The service delivery level is an important level of reporting on stock shortages as this is a critical point and will determine whether or not the beneficiaries of the programme receive the life-saving vaccines.

The incidence and duration of stock-outs are best measured at the lowest level in the supply chain. However, countries may not have adequate information systems to adequately report vaccine shortages and their duration, back up the supply chain. Hence the need for investments to strengthen logistics management and the information systems within the supply chain. There is a global consensus that safety stock should be maintained at three months level.<sup>14</sup> Therefore,

the shortage at the national level, indicate that this safety stock gets depleted and the availability of stock in the lower levels in the supply chain is at risk <sup>7</sup>. Furthermore, it is doubtful that in practice, a majority or a significant number of countries can keep stock of quantities that are in line with this safety level. This is because, since the introduction of more combination vaccines, the requirements for cold chain capacity has increased with an impact of the quantities that can be stored at each level of the cold chain and certainly at service delivery level.

Major factors responsible for vaccine stock-outs at the national level and other levels of the supply chain include failure of the distribution system <sup>7</sup>, poor forecasting and stock management issues in Gavi-eligible countries, delays with procurement in middle-income countries that are not eligible for Gavi support and global vaccine shortage in high-income countries.<sup>7,14,28</sup>

Compared to other vaccines, BCG vaccines recorded the highest stock out rates at the national and district level, apart from the recent increase in shortages of polio vaccine. Shortage of BCG vaccine has been an ongoing global concern since 2013 due to decline in global availability of BCG in 2012<sup>15</sup>. This was caused by manufacturing quality problems combined with high demand, resulting in global shortages.<sup>29</sup> UNICEF, being responsible for procuring vaccines for most countries, experienced an increase in demand, especially from countries that previously self-procured their vaccines. In 2015, shortages worsened as the supply from UNICEF did not match the global demand.<sup>30</sup> This explains why more countries in the WHO African region reported national-level stock-outs of BCG in 2015. However, an update from UNICEF states that the supply for 2016-2018 is anticipated to be sufficient enough to meet the demand by countries. This probably explains the slight reduction in the number of countries reporting national level stock-outs in 2016.<sup>31</sup>

#### **2.4.2. Vaccine stock-outs at the health facility level**

Our findings highlight the considerable gap that exists in the reports of stock-outs. It is known based on anecdotes, that vaccine stock-outs do occur, but the reports of vaccine shortages at facility level are scarce. From our results, South Africa is one of the few countries that seems to have a routine survey for stock-outs at the service delivery levels ongoing since 2013.

Also, our results show that some district levels may be affected by stock-outs more than others. Therefore, variations do occur as illustrated in the reports from South Africa <sup>21-23</sup> and Nigeria <sup>19</sup>. For example, in 2014 Limpopo Province, South Africa suffered most from stock-outs in the country than Gauteng Province, South Africa. Similarly, the study from Nigeria also showed

some disparities between regions in the country with the Northern part of the country experiencing lesser stock-outs than the Southern region. The diffuse nature of the stock-outs shows that there are underlying reasons that differ by province <sup>32</sup>.

Reports of vaccine stock-outs must be taken seriously, no matter how short the duration may be. In 2015, 64 facilities out of 469 in the Eastern Cape Province of South Africa reported vaccine stock-outs. Although this may only be 14% of facilities, its impact can be significant. Each health facility is a unit, which serves a target population. This implies that stock-outs in 64 facilities will impact on thousands of people that are meant to receive their vaccines from those facilities. That is, thousands of people, mostly children, are likely to miss their vaccinations, may not return for catch-ups and may eventually be prone to vaccine-preventable diseases. This explanation also applies to other results obtained in this study.

The findings on the occurrence of stock-outs during Ebola outbreaks shows that it is crucial to ensure that there are no interruptions in routine immunisations in the face of disease outbreaks <sup>18</sup>. One factor that may have contributed to stock-outs of routine childhood vaccines during the Ebola disease outbreak could be a shift in priority, which may have influenced procurement, deliveries and the entire supply chain. Vaccine stock-outs due to outbreak of meningitis has been reported elsewhere.<sup>33</sup> This highlights the importance of having safety stocks in the facilities as this helps to cater for unforeseen circumstances, especially in situations where supplies at the higher levels are not possible.<sup>34</sup>

Introduction of new vaccines could also lead to stock-outs, as reported in the studies included in this review <sup>17,20</sup> and even elsewhere, in the Americas<sup>17</sup>. Stock-outs occurred probably due to a sudden increase in demand, which exceeded supply or in cases where catch-ups strategy are not being incorporated into forecasting predictions <sup>20</sup>.

A few limitations have, however, been observed in the included studies. Firstly, the method of data collection for the survey conducted in South Africa is prone to bias since it is done telephonically. The estimation of stock-outs using this method could lead to an underestimation of the exact frequency of stock-outs, and the respondents may not provide accurate information on vaccine stock levels.<sup>21–23</sup> Also, the study conducted in Nigeria, which used secondary data, may not be completely accurate due to poor data quality.<sup>19</sup>

## **2.5. Conclusion and recommendations**

This study shows that significant levels of vaccine stock-outs still occur at different levels in the supply chain in many countries in the African region. With national-level stock-outs being able to cause an interruption in immunisation services at the facility level. Also, facility-level stock-outs, despite being underreported, still occur. The proportion of facility-level stock-outs can vary between provinces in the same country. Poor vaccine stock management, new vaccine introductions, disease outbreaks and delays in deliveries, poor supply chain structure and lack of skilled personnel can contribute to stock-outs at the facility level. More studies are needed to know the magnitude and extent of vaccine stock-outs. Also, there should be interventions targeting causative factors.

African countries need to explore specific interventions for improving vaccine availability. For example, interventions to improve forecasting and stock management at all levels of the supply chain <sup>35–40</sup>. Researchers need to identify, develop and evaluate innovations to enhance the availability of vaccines. This underscores the need to build the research capacity of countries in Africa <sup>2</sup>. Countries need to assess and identify the factors that can help to prevent stock-outs in different areas, especially those areas most affected by stock-outs. Countries should strengthen immunisation supply chains via innovative ways of ensuring that the supply of vaccines to health facilities are without hassles. Such innovations need to allow for timely and consistent data visibility and availability. Furthermore, countries should take the process of effective vaccine management (EVM) more seriously. The EVM helps countries assess the performance of their vaccine supply chain (different areas of the supply chain) to identify strengths and weaknesses and ensure the designing and implementation of tailored plans to address the weaknesses.

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## CHAPTER THREE

### Vaccine stock management in primary health care facilities in OR Tambo District, Eastern Cape

This manuscript has been submitted to *Vaccine*.

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### **3.0. Abstract**

#### **Background**

Vaccine stock management includes the processes undertaken to ensure that vaccines are continuously available in the right quantities and quality at any point in time in the health facilities. Poor stock management has been identified as one of the causes of vaccine stock-outs in health facilities. This study assessed the occurrence of vaccine stock-outs and vaccine stock management practices in primary health care facilities in OR Tambo district of the Eastern Cape province, South Africa.

#### **Method**

The descriptive cross-sectional study design was used in this study to assess both the stock management practices and the availability of vaccines in the facilities. The study was conducted in 64 primary health care facilities across all sub-districts in OR Tambo. Data were collected using a questionnaire administered by the researcher, record checks and through observation. The occurrence of stock-outs of six tracer vaccines on the day of the visit in the past 24 months were assessed. The data were captured into REDCap tool and analysed using STATA version 14.

#### **Results**

Both stock cards and the stock visibility solution (SVS) device were used in all the facilities for vaccine stock management. The stock cards were mainly used for recording vaccine transactions while the SVS mobile device was used to report stock levels to the managers at district and provincial level. Less than half of the facilities visited 27 (44%) filled their stock cards regularly. Only about half 31(49%) of the respondents understood the concept of maximum and minimum stock levels, which are needed for proper quantification of needs. Delays in receiving supplies from the pharmaceutical depot were commonly reported by facilities, which could have contributed to stock-outs. Most of the facilities (77.6%) reported that the lead time was between one to three months. Common reasons for delays from the depot include staff shortages at the pharmaceutical depot causing a backlog of orders, delay from the suppliers, procurement delays and possibly lack of proper communication between the depot and the facilities. The first to expire first out (FEFO) principle was practiced in 41(73%) facilities.

A total of 49 (77%) health facilities had at least one stockout for at least one vaccine on the day of the visit. Furthermore, BCG and OPV were the most commonly affected vaccines in 37 (58%)

and 28 (44%) of facilities, respectively. BCG and OPV had the most prolonged median duration of stock-out of 167 and 103 days, respectively. Amongst the newer vaccines, PCV had the most prolonged duration of stock-outs, with a median duration of stock-outs of 85 days.

## **Conclusion**

The lack of proper stock management and the associated use of manual stock cards and long response time from the pharmaceutical depot may be responsible for stock-outs in the primary health care facilities in OR Tambo District. Interventions for improving vaccine availability should be considered. In particular, those focused on improving vaccine stock management, vaccine supply and human resources.

**Key words:** Vaccine stock management, stock-outs, inventory, immunisation, South Africa

### 3.1. Introduction

Vaccine stock management includes the processes undertaken to ensure that vaccines are continuously available in the right quantities and quality at any point and at all times in the vaccine supply chain, including health facilities. These processes include adequate forecasting, recording, monitoring of expiry dates, and proper storage of vaccines.<sup>1,2</sup> Forecasting involves calculating the right quantities to order from the supplying store based on consumption rates of a health facility. The accuracy of quantities ordered depends on the quality of the records of consumption and an understanding by the person doing the calculation and relevant contextual factors.<sup>2</sup> Indications are that a vast majority of primary health care facilities in South Africa still use stock cards to manage vaccine stock, and these can be used to obtain monthly usage data.<sup>2</sup> Accurate records of all stock transactions are essential in ensuring adequate quantities of vaccines throughout the vaccine supply chain.<sup>2</sup> The recording and monitoring of expiry dates prevent vaccine wastage, while proper storage ensures that the potency of vaccines is maintained. The national department of health of South Africa published the “Cold Chain and Immunisation Operations Manual, 2015 edition” which is a guideline on standard practices for the management of the vaccines at different levels in the supply chain, including the health facilities. This is a standard national guide for every health worker who is in charge of managing and handling vaccines.<sup>2</sup>

Poor stock management has been identified as one of the causes of vaccine stock-outs in health facilities.<sup>2–5</sup> The complete absence of vaccines at the point of service delivery, which is referred to as vaccine stock-out<sup>6</sup> is one of the serious challenges that threaten the success of immunisation programmes.<sup>3–5,7–10</sup> Vaccine stock-outs occur more often and have more impact on populations that dwell in rural areas; the majority of them depend on the public health system for their health care needs.<sup>11–13</sup> Vaccine stock-outs result in repeated and costly visits to health care facilities by health care users before they can access the vaccines. These repeated visits can cause a loss of public confidence in the health system.<sup>14</sup> Furthermore, the children who do not receive their vaccine doses timely are prone to vaccine-preventable diseases, and their communities are also at risk of disease outbreaks.<sup>3,4,15</sup>

There are a few reports that point to significant shortages of vaccines which became more common since the introduction of new vaccines in many parts of South Africa<sup>3,16</sup>. However, despite these reports, there is limited information on the actual shortages of vaccines; especially in certain parts of the country such as the Eastern Cape Province. Specifically, there is no



literature on the level of availability and stock management of vaccines in OR Tambo district of the Eastern Cape Province, one of the most rural districts in the country.

This study assessed the availability of vaccines and vaccine stock management practices in primary health care facilities in the OR Tambo district. This chapter describes the status of vaccine stock management at primary health care facilities in OR Tambo district, Eastern Cape. This study intends to add to the body of knowledge that will be relevant to inform policies around improving stock management and ultimately preventing vaccine stock-outs.

### **3.2. Objectives of this study**

- i. To assess the vaccine stock management procedures used in selected facilities in OR Tambo district of the Eastern Cape Province of South Africa.
  - ii. To establish the level and frequency of vaccine stock-outs in OR Tambo district
- To identify the vaccines more likely to be out of stock.

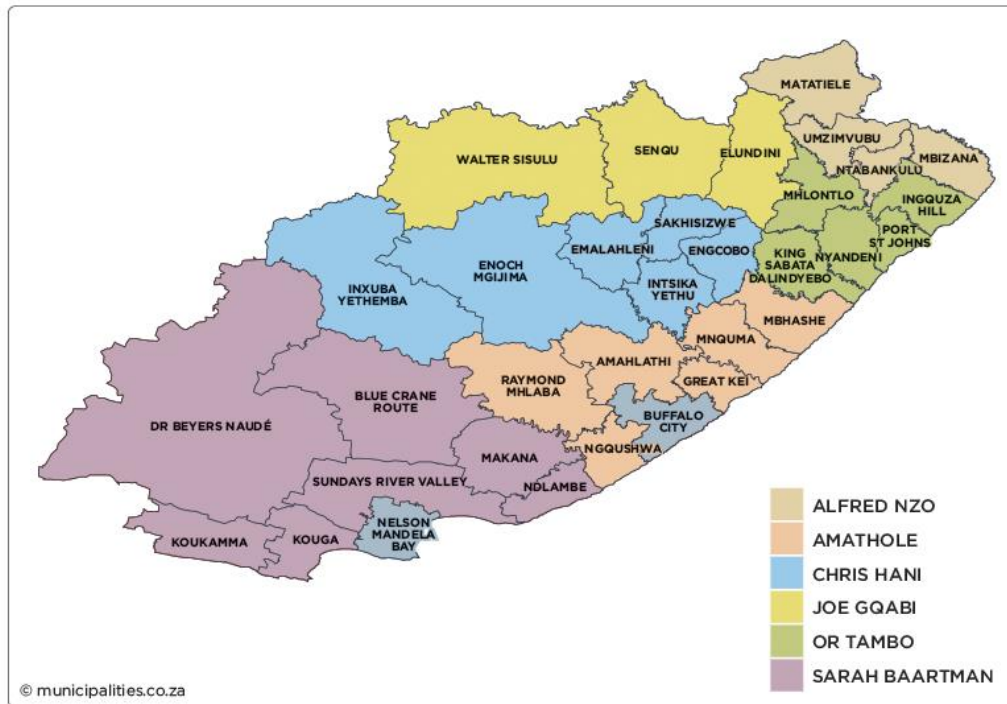
### **3.3. Methods**

#### **3.3.1. Study setting**

This study was conducted in the OR Tambo district of the Eastern Cape Province. The Eastern Cape is located on the east coast of South Africa and has eight districts. The Eastern Cape province is the second largest in South Africa and one of the poorest <sup>17,18</sup>. The 2016 estimates are that 20.8% of the 7 061 700 population of the province lives in OR Tambo District <sup>17</sup>. This district is comprised of four sub-districts; is rural and one of the poorest districts in the country <sup>17</sup>. OR Tambo district depicts a typical resource-constrained area. The district also has a poor terrain, inadequate infrastructure and because of this access to some health facilities is a challenge, even for the health workers.

OR Tambo district has a high neonatal and child mortality and a high burden of HIV/AIDS and TB. Various initiatives have been implemented to improve provision and the quality of health care services in the district. Some of these initiatives include the e-health strategy, supply chain management reforms, ideal clinic realisation. It is one of the National Health Insurance (NHI) pilot districts in South Africa.

The supply chain structure in the Eastern Cape is mostly the pull system, whereby facilities send requisitions or place orders to the pharmaceutical depot based on consumption rates.



**Figure 1: Map of the Eastern Cape Province showing districts and sub-districts**  
<https://municipalities.co.za/provinces/view/1/eastern-cape>

### 3.3.2. Participants

The sites for data collection were mainly the primary health care facilities where immunisation services are provided. Respondents for this study were nurses, pharmacists and pharmacist assistants who are employed on a full-time basis at each selected facility and involved in the management of vaccines. Each respondent represented a facility. Student nurses and private PHC clinics and their employees were excluded from this study.

### **3.3.3. Sample size calculation**

Based on the District Health Information System (DHIS), OR Tambo is comprised of 145 health facilities. We calculated a total sample size of 60 based on a hypothesised overall stock out rate of 50%, with a confidence interval width of 95% and 10% precision.

### **3.3.4. Sampling**

We used probability random sampling to sample 64 sites proportional to the number of facilities in each sub-district. A total of 64 sites were visited: 21 facilities in King Sabata Dalinyebo (KSD); 23 in Nyandeni; 7 in Quakeni and 13 in Mthlontlo.

### **3.3.5. Study design**

We conducted a cross-sectional study to assess both the stock management practices and the availability of vaccines in the facilities. Retrospective record review of stock-cards was used to check for stock-outs that occurred in the last two years.

### **3.3.6. Outcome measures**

The following outcomes were measured:

- The proportion of facilities that reported to various stock management practices such as recording and reporting systems, storage practices, management of damaged or wasted vaccines
- The occurrence of vaccine stock-outs: This was measured as the percentage of facilities that experienced a stock-out of one or more vaccines during the study period, precisely the day of the visit to the health facility. The result was expressed as a percentage of the total number of facilities [8].
- Duration (in days) of vaccine stock-outs over two years: February 2017 – February 2019. Duration of stock-outs was calculated from the day the vaccine was not available until the day the new vaccine stock was obtained or the day of the visit.

### **3.3.7. Data collection and Logistics**

Before data collection, the researcher and a co-investigator conducted a visit to the Eastern Cape province to brief and enlist the support of senior managers on the planned study. The visit was also to assist with the refining of the research questions and the questionnaire that was

used for data collection. The visit was conducted over four days from May 28 to 31<sup>st</sup> 2018. Meetings were held with Provincial senior managers. All four sub-districts were visited, and the study was introduced to programme managers. Four facilities were visited, each from one of the sub-districts. This exercise was useful in further planning, and several areas were clarified, which related to the research and was incorporated into the study and the questionnaires. During site selection, we excluded the facilities visited before the main study, to minimise bias. Also, the officials in the visited facilities neither had access to the questionnaires nor knew the information that will form part of the research questions.

Data was collected between 25<sup>th</sup> February to 15<sup>th</sup> March 2019. Data on vaccine stock management procedures in the facilities were collected using questionnaire and physical observation of vaccine stock management procedures in the participating clinics. The questionnaire was adapted from the WHO effective vaccine management (EVM) assessment tool <sup>19</sup> (Appendix 2). The questions on stock management procedures focused on following areas; procedures used for stock recording, vaccine ordering, managing and recording of damaged and expired stock, the frequency of inventory, storage arrangements and availability of vaccines. We also checked the vaccine stock records, stock at hand and records of vaccine orders. We verified if the stock cards were consistently used for stock management. The stock cards were also checked to see if they reflect: minimum or re-order level, maximum and current stock levels and vaccines received and issued. Vaccine stock-outs data were collected through physical counts of the six tracer vaccines in the fridges. The vaccines were Bacillus Calmette Guerin (BCG), measles, rotavirus (RV), pneumococcal conjugate vaccine (PCV), oral polio vaccine (OPV) and hexavalent vaccine, a combination of Diphtheria, Tetanus, Acellular Pertussis, Inactivated Polio Vaccine, Haemophilus influenza type b, Haemophilus influenza type b and Hepatitis B (DTaP-IPV-Hib-HBV). We assessed the availability of vaccines on the day of visit to the facilities. We also assessed the duration of stock-outs in the last two years (Feb 2017 – Feb 2019). The initial plan was to assess the occurrence of stock-outs and duration at least three years before and after the introduction of the SVS in order to assess the effects of the SVS on vaccine availability. Unfortunately, we could not find most of the previous years' bin cards. Since most facilities had at most two years records, we had to work with what we got.

### **3.3.8. Data Management**

Data sets from questionnaires were stripped off all personal information upon completion of data collection. Study data collected on the questionnaire was managed using Research Electronic

Data Capture (REDCap) tool hosted at the South African Medical Research Council. REDCap is a “secure, web-based application designed to support data capture for research studies.”<sup>20</sup>

### **3.3.9. Data analysis**

Data from REDCap was exported to STATA statistical software, version 14, for analysis. Data were analysed using descriptive analysis. Association between variables was determined using the chi-square test. The continuous variables such as duration of stock-outs were summarised using median since they were not normally distributed. The categorical variables were summarised using frequencies.

We tested the following hypotheses (Null hypothesis), at  $p < 0.05$  level of significance

- i. There is no difference between the proportion of facilities that reported stock-outs of vaccines across the districts and what?? We should be comparing at least 2 things. Refer to Chapter 1 comments.
- ii. There is no association between the presence of pharmacy personnel and the occurrence of vaccine stock-outs

### **3.3.10. Ethical consideration**

Before data collection, ethics approvals from the Research Ethics Committee of the Faculty of Medicine and Health Sciences, Stellenbosch University (S18/08/154), from the Eastern Cape Province Department of Health (EC\_201810\_009) and OR Tambo district. In each facility visited, we sought the consent of participants before collecting data.

Data sets from questionnaires were stripped off all personal information to maintain confidentiality.

## **3.4. Results**

### **3.4.1. Response Rate**

A total of 64 selected public health facilities were visited. Although we had two facilities that declined to participate, they were replaced with other facilities closest to them. Therefore, the

overall response rate for this study is 100% (64/64). Table 1 below shows the number of facilities visited per sub-district.

**Table 1: Number of facilities visited in the OR Tambo district**

<b>Sub-district</b>	<b>Number of facilities visited</b>
KSD	21 (32.8%),
Nyandeni	23 (35.9%)
Quakeni	7 (10.9%)
Mthlontlo	13 (20.3%)

### **3.4.2. Characteristics of facilities visited in OR Tambo district**

All four sub-districts in OR Tambo which have a total of 146 facilities participated in the study. Table 2 shows other characteristics of the facilities visited; the position of respondents, pharmacy personnel and the type of storage equipment used. There was a total of 28 (44%) pharmacist's assistants in all the facilities visited, 2 (3%) pharmacists and 34 (53%) were nurses who were vaccinators or facility managers. Districts with more facilities had more pharmacy assistants. For example, 23 facilities were visited in Nyandeni, and this district had 11 pharmacist's assistants.

**Table 2: Characteristics of facilities visited in OR Tambo district**

Pharmacy personnel					Position of respondents				Type of storage equipment			
Sub-district	Pharmacist	Pharmacy assistant	Both	None	Pharmacist's assistant	Pharmacist	Vaccinator	Facility manager	Vaccine fridges (chest like)	Vaccine fridges (upright)	Glassdoor	Ordinary domestic
KSD	0	7	1	13	6	1	12	2	5	4	0	11
Nyandeni	0	11	0	12	9	0	8	6	6	2	0	9
Quakeni	0	4	0	3	4	0	1	2	3	1	1	3
Mthlontlo	1	6	0	6	5	1	4	3	3	8	0	3
Overall Facilities n(%)	1 (2%)	28 (44%)	1 (2%)	34 (53%)	24(3%)	2 (3%)	25 (39%)	13 (20%)	17(27%)	15 (23%)	1 (2%)	36 (56%)

### **3.4.3. Stock management practices**

#### **Recording and reporting systems and practices**

Both stock cards and the stock visibility solution (SVS) devices were used in all the facilities for capturing vaccine stock levels. The stock cards were used to record vaccines movement and utilisation while the SVS mobile device was used to report on stock levels to the managers at a higher level, mainly provincial level. Only one facility was found to be using a desktop computer to capture vaccine stock.

The stock cards had sections for the following information: name of the vaccine, dosage form, and strength, quantity ordered, requisition number, to/from where orders were received or transferred to, quantity received, quantity issued, stock balance, unit price and remarks (Figure 1). They also have sections for re-order level, and total monthly issues and consumption levels. However, stock cards did not have fields for recording batch number, expiry date and VVM status of vaccines in keeping with the standard set in the Cold Chain Manual. Less than half of the facilities visited, 27 (44%) filled their stock cards regularly, at least up to one week before the study. Only nine (14%) facilities had physical stock closely matching with stock on the stock cards. Approximately half (49%) of the facilities had separate stock cards for measles vaccine and its diluent.

Furthermore, only 26 (43.3%) facilities recorded expiry dates and 32 (50%) facilities recorded batch numbers of vaccines. Even though there were no fields for bath number of vaccine vials, on the stock cards, some facilities made use of the 'remarks section'. No facility had records of the VVM status of vaccines on their stock cards because the provision was not made for this information on the stock-cards. There was no other record that indicated the VVM status of vaccines.



Product name: HEXAVALENT (VACCINE COMBINATION) Card No: 01  
Strength: 0.5 ml Dosage form: V.V.M Issue and Serial Number: 121922607  
or Size: \_\_\_\_\_

RECORD OF ORDERS, RECEIPTS AND ISSUES

Date	Requisition No.	Quantity ordered	Voucher No.	Qty From	Quantity received	Quantity issued	Stock balance	Unit Price	Remarks
27/06/16							320	0.5	Initial Stock
27/06/16				Disp	03	27			10/06/16
27/06/16				Disp	05	22			10/06/16
27/06/16				Disp	18	10			10/06/16
27/06/16				Disp	10	0			10/06/16
27/06/16				Disp	20	20			10/06/16
27/06/16				Disp	07	13			10/06/16
27/06/16				Disp	500	573			10/06/16
27/06/16				Disp	10	503			10/06/16
27/06/16				Disp	10	493			10/06/16
27/06/16				Disp	10	483			10/06/16

TOTAL MONTHLY ISSUES

Fiscal year	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	Usage	Expired
FY 16/17			7	20	41	55	40	53	56	60	125	27		07/2017
FY 17/18	100	100	80	205	200									
FY 18/19														

**Figure 1: Photo of the stock card used in all facilities in the Eastern Cape Province, South Africa.**

### Knowledge and record of maximum and minimum stock levels on the stock cards

Among facilities visited, 31(49%) of respondents understood the concept of maximum and minimum stock levels. Furthermore, it was observed that 24(39%) and 25(40%) of facilities, recorded minimum and maximum stock levels on stock cards, respectively.

### Vaccine ordering and lead/response time

The requisition booklets were used in all the facilities for placing orders to the pharmaceutical depot. We sought their responses regarding the response time, that is, how long it took for the facilities to receive supplies from the pharmaceutical depot once an order is placed. Facilities reported they experienced delays: 45 (77.6%) facilities reported that lead time took between one to three months; 10 (17%) reported that their lead times ranged between two to three weeks. All facilities reported that they placed an emergency ('special') orders while waiting for their main supplies from the depot. Special orders that are generally for a maximum of five items are usually placed whenever there is an urgent need for items while waiting for bulk orders to be supplied by the depot. The working norm is that a person from the facility placing a special order goes to the depot to pick and collect the special order. As a result, special orders were received on the same day. Also, some facilities had to send their pharmacist's assistants to pick their bulk orders. If this did not happen the lead time was longer than two or three months. It was observed that a majority of facilities place special orders weekly and, in many facilities, the understanding and the standard was that special orders are routine and are placed weekly.

Twenty-six (42%) facilities reported that the quantities they ordered were sometimes reduced by the depot. The vaccines mostly reduced were BCG and OPV. Other vaccines were reduced depending on the availability at the depot. Also, in most instances, they do not receive matching quantities of measles vaccine and the diluent. A few facilities did not know that they had to order measles diluent separately.

#### **Reasons for long response times from the pharmaceutical depot**

On the issue of long response time from the depot, we had a conversation with the staff of the depot. They highlighted the following reasons why facilities experience delays with their orders; the primary reason is the backlog of orders at the depot. These backlogs are caused by staffing issues. The discussion elicited that the depot was experiencing staffing challenges coupled with the ongoing renovations, which made working conditions a challenge. The staff shortages generally meant that the facilities had to send their pharmacist's assistant or someone to the depot to do the picking of vaccines, and if this did not happen the delays will be much longer than two months or more.

Another concern expressed by the depot officials was the 'erratic' orders from the facilities. The facilities make inconsistent orders, sometimes very high and sometimes low, which could be attributed to their inability to calculate their maximum and minimum stock levels. Also, some facilities tend to order in excess from the depot when there are issues of undersupply to the depot. As a result, the stock levels at the depot may not be enough to serve other facilities. Delays were also caused by shortages from the suppliers. Other reasons reported were delays in procurement on their part, which relates to the staffing issues. Furthermore, the electronic stock management system malfunction sometimes occurs, causing delays in procurement by the depot and eventually resulting in longer response time for the facilities. The depot staff highlighted a gap in communication between the depot and the facilities as one of the contributing factors for delays and inefficiencies in supplying the facilities with their needs.

#### **3.4.4. Assessment of storage practices in the facilities**

Upon observation, the first to expire first out (FEFO) principle was practiced in 41(73%) facilities. Of the 36 facilities that use domestic fridges, 8(22%) store vaccines in the vegetable drawer. There were expired vaccines in 6 (11%) of facilities. The vaccines that had just expired and were mostly the hexavalent vaccine. Eleven (20%) facilities had frozen vaccines whereas 9

(15%) facilities had vaccines that had reached the VVM discard point. Most of the frozen vaccines were in the domestic fridges. The quantities of measles vaccines and their corresponding diluents matched in 16 (29%) facilities. In one facility rabies vaccine was stored in the freezer.

#### **3.4.5. Disposal of Damaged or expired stock**

When the respondents were asked if they knew the procedure to follow for managing vaccine wastage, half 32(51%) reported that they knew how it is done. Thirty-seven facilities (59%) reported that they had records of wastages. However, upon verification, only a few (how many) facilities had reports of vaccine wastages in the previous year.

When the respondents were asked to explain the procedure of managing damaged vaccines, there were varied responses. Most of them reported that they filled the 'incident form' firstly before disposing the expired or damaged vaccines into the waste bucket which were picked up by a private waste disposal company. Other respondents said they would phone the district pharmacist who would pick damaged items up, after filling the waste indicator forms and disposing into the waste bucket. Most of them reported that they hardly experienced wastage; they experienced stock-outs more than wastages. We also asked if they knew how to calculate vaccine wastage, 30(49%) said they did. Also, 38(67%) facilities reported that they did not know that they were supposed to report wastages to managers.

#### **3.4.6. Availability of vaccines in the facilities in OR Tambo district**

A total of 49 (77%) health facilities had at least one stockout for at least one vaccine on the day of the visit. Furthermore, BCG and OPV were the most commonly affected vaccines with 37 (58%) and 28 (44%) facilities seen to have experienced the stockouts of these vaccines, respectively, on the day of the visit. Amongst the newer vaccines, nine (14%) of facilities had RV stock-out while eight (13%) facilities had stock-outs of measles vaccines on the day of the visit. However, in the last two years (February 2018-February 2019), apart from BCG and OPV having the longest median duration of 167 and 103 days, respectively, PCV experienced the longest duration of stock-outs of 85days, amongst the newer vaccines. Table 5 shows the median duration of vaccine stock-outs in the affected facilities.

Table 2 shows the occurrence of vaccine stock-outs on the day of the visit of across each sub-district. KSD had the highest percentage of facilities occurrence of 86%, while Quakeni sub-

district had the lowest occurrence, of 29%. However, Pearson's chi-squared test for the difference in the occurrence of stock-outs across the sub-districts yielded a p-value of 0.02. We, therefore, reject the null hypothesis. This implies that there is a significant difference in the occurrence of vaccine stock-outs across the sub-districts. The differences observed could be attributed to the different sample sizes for each sub-district. The sub-districts with high number of facilities visited experienced more stock-outs.

The Pearson's chi-squared test for association between the presence of pharmacy personnel (pharmacy assistant or pharmacist or both) and the occurrence of stock-outs yielded a p-value of  $p = 0.3$ . Hence, we fail to reject the null hypothesis. Therefore, there was no association between the occurrence of vaccine stock-outs and the presence of any pharmacy personnel. Surprisingly, the sub-district with the higher number of pharmacy assistants, which one, mention it experienced more vaccine stock-outs.

**Table 3: Percentage of facilities reporting stock-outs per sub-district on the day of visit**

<b>Sub-district</b>	<b>n (%)</b>	<b>95% CI</b>
Total number of facilities (N)		
KSD (N=21)	18(86)	63-96
Nyandeni (N=23)	19(83)	61-94
Sub-district 3 (N=7)	2(29)	6-70
Sub-district 4 (N=13)	10(77)	46-93
Overall stock out n (%)	49 (77)	64 – 86

**Table 4: occurrence of vaccine stock-outs in the facilities on the day of visit**

Vaccine	Number of facilities with stock-outs	Percentage of facilities (95% CI)
BCG	37	58% (45-70)
Measles vaccine	8	13% (6-23)
Rotavirus vaccine (RV)	9	14% (7-25)
Pneumococcal conjugate vaccine (PCV)	3	5% (1-13)
Hexavalent	3	5% (1-13)
Oral Polio vaccine (OPV)	28	44% (32-56)

**Table 5: Duration of stock-outs of vaccines in the primary health facilities in OR Tambo in the last two years (Feb 2017 – Feb 2019).**

Vaccine	Median days	Interquartile range, Q1-Q3
BCG	167	71-299
Measles	44	1-74
Rotavirus	61	21-80
Hexavalent	72	27-151
PCV	85	33-140
OPV	103	60-210

### 3.5. Discussion

According to the WHO, the concept of an ideal vaccine stock management system is one that ensures that vaccines are of assured quality when they are received, are always in the right quantities at all times and stored appropriately with proper maintenance of the cold chain.<sup>1</sup> This study describes the stock management practices in primary health care facilities in OR Tambo district, Eastern Cape, as well as the occurrence of vaccine stock-outs.

This response rate achieved in this study is in line with the 2014 Stop Stockout Project (SSP) survey conducted in South Africa, where 98% responded to the survey as compared to 100% in this study.<sup>14</sup> This high response rate increases the validity and generalizability of the findings to the entire district.<sup>21</sup>

Our findings on the status of vaccine availability in the primary health facilities in the study area indicate that a high proportion of facilities experience vaccine stock-outs. These level of stock-outs in this study(on the day of visit) at 77% of facilities that experienced stock-outs is higher than that of another study conducted in another province in South Africa, where 29% of facilities experienced vaccine stock-outs.<sup>3</sup> Other countries have also reported a much lower proportion, such as 8% in Ethiopia; 51% in Kenya<sup>22</sup> and 6.7% in Tanzania.<sup>23</sup> Similarly, our findings are much higher than those of the stop stockout project (SSP) in the Eastern Cape, where the authors used a different method. According to the SSP 2016 reports, 14% of facilities in the Eastern Cape reported stock-outs of vaccines on the day the telephonic survey.<sup>16</sup> However, the methodology of this study of phoning and enquiring about stock out on that particular day can be expected to show a much lower shortage.

The proportion of facilities that reported stock-outs of hexavalent vaccine in this study (5%) is almost similar to that of the 2017 report by the SSP<sup>24</sup>. However, the occurrence of stock-outs of rotavirus (4%) and measles vaccines (2%) as reported by the SSP in 2017 are much lower than in this study where we found 14% and 13% respectively. The stock-outs data from this study was based on physical counts, while the SSP was based on a telephonic survey. The most affected vaccines are BCG and OPV, and other studies have reported the same.<sup>25</sup> The stock-out of BCG should be related to global shortages that have been ongoing since 2012 due to problems with procurement problems combined with high demand.<sup>26,27</sup>

With regards to stock management, most of the facilities visited seem to be reluctant to fill the stock cards. A vast majority of stock cards were not updated; minimum and maximum stock levels were neither recorded on the cards nor used as a basis for ordering of vaccines. Most of the participants lacked adequate knowledge of the standard procedure for ordering vaccines. Although not explicitly asked in many facilities, there was an indication that few pharmacist's assistants had special training on vaccine management. According to the national department of health cold chain manual, the minimum levels and maximum levels of vaccines need to be set for every vaccine in order to adequately quantify needs and aid in determining quantities to order<sup>2</sup>. The minimum stock level is the level below which vaccine stocks should never drop without having placed an order. It is the amount of stock that will be used in the time between placing and receiving an order plus the reserve or safety stock that is kept for emergencies and unanticipated demand or delivery delays.<sup>2,28</sup> Setting the minimum stock levels for every vaccine guards against experiencing shortages or stock-outs in the facilities. The maximum stock level, on the other hand, is set to guard against oversupply, which results in losing vaccines to expiration before they can be used. The maximum stock level is the amount needed to meet demand until the next order is received, taking into account factors that play out between placing of orders and receiving them. For example, lead time, delays etc.<sup>2</sup> Both maximum levels and minimum stock levels are calculated from historical stock data, which is usually obtained from the stock cards. When stock cards are not regularly updated, such data is not available, and the facility runs the risk of stock-outs or overstocking. There are also other reports that health facilities are not able to quantify their needs and keep updated stock records.<sup>13,29–32</sup> It may, therefore, be necessary for policymakers to consider replacing the stock cards with electronic stock management systems such as the Rx solution which is mostly used in hospitals. The Rx solution has advantages over the paper-based system of stock management. With electronic stock management, there is better tracking of stock movement, including batch numbers and expiry dates of medicines. Also, there is automated ordering of vaccines; the Rx solution can automatically recommend quantities of items to be ordered based on historical data,<sup>33–35</sup> which is not easily obtainable with the stock cards. This can solve the challenges of improper forecasting. It will be essential to harmonise the functions of both the Rx solution with the SVS to avoid duplication of efforts for health workers; by designing a single system for stock management in the facilities and reporting of stock levels to the managers.

The depot faces some challenges which complicate the challenges faced by the facilities and the weakness of the system, resulting in delays in delivery of the supplies to facilities. The

facilities reported that there are frequently delays in the delivery of supplies from the depot. It appeared that facilities that had transport and had a pharmacist's assistant to go to the depot to pick their orders were in a better position to ensure the adequacy of stock. However, this information was not specifically asked for, and this could not be analysed. In some instances, their supplies are reduced by the depot. The staff at the pharmaceutical depot highlighted that the depot suffers staff shortages which have led to backlogs of orders from the facilities and hence may not be able to meet up with the demand from the facilities. Secondly, delays could be caused by shortages experienced by the suppliers.

The depot confirmed the reduction of orders sent by the facilities and the reason is that they perceive that the facilities order more than their needs, in anticipation of stock-outs. The depot reduces orders in order to conserve stocks and ensure that the available stock is enough for other facilities. Excess ordering could occur when there is a sudden increase in demand from the facilities, in cases of outbreaks, for example, where the facilities will need to perform immunisation campaigns. All the issues highlighted above, including staff shortages, adjustments of quantities ordered by facilities (which was also reported in a previous study conducted in this same depot in 2013), imply that these challenges have been persistent.<sup>36</sup> A qualitative study conducted in one of the provinces of South Africa highlighted a gap in communication as one of the factors that influence stock management in the health facilities.<sup>37</sup> The communication between the depot and the facilities must be strengthened in order to solve these challenges.

Human resource constraints can have been identified to be one of the significant causes of supply chain-related problems,<sup>38</sup> including poor stock management.<sup>3,39–41</sup> This is probably one of the reasons for poor stock management noted in this study. Vaccine stock management was handled by nurses in facilities where there were no pharmacy assistants. As with other studies, there were more facilities with nurses responsible for pharmaceuticals, and fewer had pharmacy assistants in the facilities visited.<sup>3,37,42</sup> Generally, nurses were not trained in vaccine stock management; they might have been merely orientated.

The issue of nurses taking up the responsibility of managing pharmaceuticals is a challenge because it interferes with their primary clinical duties in the facilities. Nurses feel overwhelmed by the excess workload that comes with management of pharmaceuticals.<sup>3</sup> It is therefore essential to recruit more pharmacist assistants who will be dedicated to the stock management of vaccines and other medicines. On the other hand, the policymakers may consider proper



training and refresher training for the nurses on the management of pharmaceutical. Such training should have specific focus on management of vaccines since these have specific qualities and requirements. One option could be to include management of pharmaceuticals as part of the compulsory professional development for nurses.<sup>37</sup>

Vaccines are meant to be administered well before their expiry date is reached. The vaccines and diluents must be arranged in such a way as to maintain the FEFO stock management system.<sup>2,28</sup> Most facilities understood and adhered to this principle as compared to another study where none of the facilities was adherent.<sup>43</sup> There were more domestic fridges than the vaccine fridges in the facilities visited, as it is the case in most facilities in South Africa.<sup>2</sup> The number of domestic fridges in the facilities was more than what was reported in another study.<sup>43</sup> The use of the domestic fridges may be why some facilities visited had frozen vaccines. All facilities ideally should be using the standard vaccine refrigerators, but when domestic fridges are used, it is expected that the temperatures be monitored continuously.<sup>2</sup> Domestic fridges are being used in primary health care facilities probably due to lack of resources, but policymakers must invest in proper storage equipment to avoid accidental freezing seen in some of the facilities visited.

### **3.6. Conclusion**

Significant stock-outs occur in the primary health care settings in the OR Tambo district. These stock-outs could be linked to poor vaccine stock management, particularly in the area of record-keeping and quantification of needs. Stock-outs caused and aggravated by long lead times experienced by the facilities and a gap in communication between the supplying depot and the facilities. There is a need to explore multipronged interventions that could be used to improve vaccine stock management in primary health care facilities. These interventions should target the entire supply chain system, human resource and tools used for stock management in the facilities.

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## CHAPTER FOUR

### A scoping review of interventions for vaccine stock management in primary health care facilities

This article has been published in *Human Vaccines and Immunotherapeutics*.

**Citation:** Iwu CJ, Jaca A, Abdullahi LH, Ngcobo NJ, Wiysonge CS. A scoping review of interventions for vaccine stock management in primary health-care facilities. *Hum Vaccin Immunother*. 2019. DOI: 10.1080/21645515.2019.1607130.

**Article's link:** <https://doi.org/10.1080/21645515.2019.1607130>

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## **4.0. Abstract**

### **Introduction**

One of the challenges facing the success of immunization programmes is shortages of vaccines at health facilities, which could result from inadequate vaccine stock management. Several approaches have been designed by countries to improve vaccine stock management. This review summarises currently available information on interventions for vaccine stock management.

### **Methods**

We considered both randomised trials and non-randomised studies eligible for inclusion in this review. The following databases were searched: PubMed, Embase, Cochrane Central Register of Controlled Trials, World Health Organization Library Information System, Web of Science, PDQ-Evidence. We searched the websites of the World Health Organisation, Global Alliance for Vaccine and Immunisation, PATH Vaccine Resources Library, and United Nations Children's Fund. The reference lists of all the included studies were also searched. Two authors independently screened search outputs, reviewed full texts of potentially eligible articles, evaluated risk of bias, and extracted data; resolving disagreements through consensus.

### **Results**

Four studies met our inclusion criteria (three before-after studies and one randomised trial). Three studies were conducted in low- and middle-income countries, while one was conducted in Canada (a high-income country). All the studies had various limitations and were classified as having a high risk of bias. Study findings suggest that use of digital information systems to improve information and stock visibility, coupled with other interventions (such as training of health care workers on the use of innovative tools and redesign of the supply chain to tackle certain bottlenecks) have the potential to increase vaccine availability, reduce response times, and improve the quality of vaccine records.

**Key words:** Vaccine stock management, vaccine stock-out, vaccine availability, primary health care facilities, e-health, supply chain



#### 4.1. Introduction

Vaccine supply chains play an important role in ensuring functional immunisation services and are therefore an important element of ensuring access to primary health care services <sup>1</sup>. The vaccine supply chain is fundamental to a good health system, and it should be designed to ensure consistent and uninterrupted supply of vaccines <sup>2</sup>. However, many children, especially in low and middle-income countries, do not always get vaccines when they present to health facilities <sup>3,4</sup>. Shortages of vaccines at service delivery points have serious consequences for the healthcare system and its users. Vaccine shortages undermine the commitment by many countries to the benefits of life-saving vaccines and universal access to quality primary healthcare services<sup>5</sup>.

Immunisation programmes in many countries are currently characterized by new vaccine introduction and efforts by countries to improve vaccine coverage <sup>6</sup>. While the introduction of new vaccines is a progressive step towards achieving the Sustainable Development Goals for health; it creates new challenges. A smooth introduction of new vaccines, which often is an expansion of national schedules with additional antigens, demands upgrading of systems, processes and infrastructure. However, in many countries, these upgrades are not in place before new vaccines are introduced.

New vaccines place a huge demand on cold chain capacity. For example, in Ethiopia, the introduction of pentavalent, pneumococcal conjugate and rotavirus vaccines resulted in a five-fold increase in cold chain capacity requirement<sup>7</sup>. Some low and middle income countries (LMICs) have reported a 10-fold increase in value of vaccines<sup>5</sup>. Many LMICs have vaccine supply chains and management systems that over decades have remained unchanged, with no corresponding increase in capacity and with no upgrade of the technology and information systems <sup>7,8</sup>. The interplay of these factors, which includes: increased cold chain requirements, the increase in contextual factors such as increase in targeted populations as well as a significant number of outreach (mobile) service points require vigilance in management of vaccine stock, to avoid vaccine shortages at service delivery points. Effective management of vaccine supply chains may be better achieved with the support of technology and upgrade of other systems. It is due to these underlying factors that several countries experience vaccine shortages with the introduction of new vaccines<sup>9-11</sup>.

Vaccine stock-out is said to occur when there is complete absence of a particular vaccine or different vaccines<sup>12</sup>. The frequency and duration of stock outs are indicators commonly used to

measure vaccine availability<sup>13</sup>. When stock outs occur, children often miss their vaccinations which in turn reduces immunisation coverage<sup>14</sup>. In LMICs, vaccine stock outs are usually caused by poor stock management which includes poor recording of vaccine inventory, poor forecasting of demands, delays and or mistakes when placing orders as well as failure to establish actual stock levels before placing orders<sup>14,15</sup>.

To improve vaccine availability at health facility level, detailed and correct information on stock levels and information on other records are required<sup>14</sup>. Innovations in the vaccine supply chain are critically needed to reduce vaccine stock-outs<sup>16</sup>, and to this effect, countries have designed approaches to improve vaccine stock management. One of such innovations is the use of digital tools to improve information or visibility of vaccine stock within the supply chain. These devices readily provide information such as: stock-on-hand and the quantity received, dispensed, and wasted<sup>17</sup>. For example, dash boards and mobile devices are used by LMICs to improve vaccine stock management and also monitor vaccine availability<sup>18–20</sup>. Other interventions that have been used to improve vaccine stock management include redesigning the supply chain and training of health personnel<sup>21</sup>. This scoping review is aimed at identifying and assessing the effectiveness of interventions for improving vaccine stock management in primary healthcare facilities. To the best of our knowledge, no review has been conducted to assess the effectiveness of these interventions.

## **4.2. Methods**

### **4.2.1. Inclusion criteria**

This review was registered in the International Prospective Register of Systematic Reviews<sup>22</sup> and the protocol was published in a peer-reviewed journal<sup>23</sup>. The following study designs were eligible for inclusion in this review, randomized trials (with randomization at either individual or cluster levels), controlled before-after studies, interrupted time series studies and repeated cross-sectional studies with no restrictions on language and publication status. The target population is healthcare facilities where vaccines are administered, and healthcare workers involved in providing immunisation services.

We considered the following interventions in our inclusion criteria:

- Interventions directed at providers of immunisation services such as education or training, audit and feedback, use of prompts and reminders, and supportive supervision.

- Interventions for monitoring vaccine stock level at facilities e.g. using mobile devices including hand held devices and cellular phones or hotline platforms.
- Interventions targeting the health system offering immunization services such as re-designing vaccine supply chain system, and integration of interventions with other services.
- Other interventions intended to reduce vaccine stock-outs, including multi-component interventions.

We considered the following as eligible comparisons: standard vaccine stock management practices in the study setting, alternative interventions, and similar interventions implemented with different degrees of intensity. We were cognizant of the fact that a standard vaccine stock management practice in one context may differ in another setting.

Our primary outcomes of interest were as follows:

- Vaccine availability: The proportion of vaccination days in which all vaccines in the national schedule were available, and no one eligible for vaccination was turned back because of stock out of vaccines, i.e. did not reach zero-stock or as defined by the authors.
- Stock-outs: The percentage of facilities that experienced a stock-out of a specific vaccine(s) that a site is expected to provide, at any point, within a defined period.

We also considered the following as our secondary outcomes:

- Inventory accuracy rates: The accuracy of data on product stock levels at a facility; that is, a measure of how stock balances recorded on a stock ledger, stock cards or automated systems are similar to the actual inventory on hand.
- Response time: The average time it takes between placing an order from a health facility to a higher facility (e.g district or provincial store) and when the order is received. Response time is also referred to as order lead time or replenishment time.
- Effective vaccine management (EVM) score: The EVM assessment is an approach used to assess the performance of the immunization supply chain at different levels from the national to the service delivery levels. The threshold for good performance is a score of 80% WHO/UNICEF 2014<sup>24</sup>.

- Cost of intervention
- Adverse outcomes of the intervention
- Acceptability of the intervention, as defined by the authors of the study.

#### **4.2.2. Search strategy**

We developed a comprehensive search strategy for peer-reviewed studies and grey literature. We searched the following databases between June and August 2018: PubMed and Embase. In addition, we searched the websites of the World Health Organisation (WHO), Global Alliance for Vaccine and Immunization (GAVI), PATH Vaccine Resources Library, United Nations Children's Fund (UNICEF) and the International Clinical Trials Registry Platform (ICTRP) for trials. We screened the reference lists of all the included studies and related systematic reviews for other potentially eligible primary studies. We also performed a citation search for all studies that have cited included studies.

#### **4.2.3. Data collection and analysis**

Two authors (CJI and AJ) independently screened the titles and abstracts of the retrieved records to identify potentially eligible studies. The full texts of these potentially eligible studies were assessed using the pre-specified eligibility criteria. The two authors met to compare lists of included studies and resolved discrepancies by discussion and consensus. A data collection form was designed and used independently by two review authors (CJI and AJ) to extract data from the included studies. Disagreements were resolved through discussion, and a third author (CSW) arbitrated when the two authors failed to reach consensus. The following information was extracted from each included study; study setting (city and country), type of study, study participants, types and description of the intervention, comparator, and study outcomes.

Two authors (CJI and AJ) independently assessed risk of bias in the included studies, using the criteria suggested by the Cochrane Effective Practice and Organisation of Care (EPOC) risk of bias tool <sup>25</sup>. This tool is based on nine domains namely random sequence generation, allocation concealment, similar baseline outcome measurements, similar baseline characteristics, incomplete outcome data, adequate prevention of knowledge of the allocated interventions, protection against contamination, selective reporting and other potential sources bias. Of these nine domains, random sequence generation and allocation concealment were not used to assess risk of bias in the non-randomised studies. Each domain was judged as either low risk, high risk, or unclear risk. Each non-randomised study was judged to have low risk of bias if it

scored “low risk” for at least one of the following three domains: completeness of outcome data, similarity of baseline characteristics, and similarity of outcome characteristics. A non-ransomised study was considered to have high risk of bias if it scored “high risk” for at least one of the three domains mentioned above. Differences in judgement were resolved by discussion between the authors and consensus, and there was no need for arbitration by a third author (CSW). Due to heterogeneity in the methods and outcome measures between the included studies, we could not conduct meta-analysis, hence we synthesized our data narratively.

### 4.3. Results

Our literature search yielded 5,462 records, out of which 5,459 were found through database searching and three through other sources. We excluded 5,455 clearly irrelevant records and assessed the full texts of the remaining seven articles for eligibility. Four studies met our inclusion criteria- three before-after studies and one randomised trial<sup>4,26–28</sup>. The reasons for excluding the three remaining studies<sup>21,29,30</sup> are provided in Table 1. Figure 1 is a flow diagram showing the process of study selection<sup>31</sup>.

One before-after study by Gilbert et al, in 39 facilities in two districts of Uttar Pradesh in India, assessed the effects of a combination of three interventions<sup>4</sup>. The first intervention was the use of a standardized data collection process. This data collection process involved the use of papers to record the quantities of vaccines used in every immunization session. This information was then pooled together and captured into a digital software for monitoring of vaccine stock levels in real time using mobile phones, tablets, or computers. For the second intervention, the district level staff were assigned the responsibility of overseeing vaccine stock management activities across various facilities, to ensure that vaccines do not run out of stock or are not stocked in excess. The third intervention involved the training of the health workers at the facilities on the use of the both the standardised manual and digital tools. The interventions improved vaccine availability and reduced replenishment time. The impact was more in low-performing facilities, where vaccine availability increased from 91% to 99%. The average replenishment time reduced from 5 to 2 days<sup>4</sup>.

The second before-after study which was conducted in Benin and Mozambique by Prosser et al involved redesigning the supply chain system<sup>26</sup>. This redesign process involved the reduction of a four-level supply chain structure to a three-level structure. In a typical four-level system, supply of vaccines begins from the national store (level 1), through the provincial level (level 2)

and districts or subdistricts (level 3), to the health facilities (level 4) where they are administered to the target population. In both countries level 3 was removed and vaccines were delivered directly from level 2 to the healthcare facilities (37 in Benin and 111 in Mozambique). Additional transport systems were created, and logisticians were assigned to supervise these activities and ensure that vaccines were successfully delivered to the health facilities. The study observed a reduction in vaccine stock-outs from 79% to less than 1% in Mozambique, and an increase in the effective vaccine management score (EVM) from 52% to 65% in Benin. The study conducted in Mozambique measured the effect of the intervention on vaccine stock-outs rates and cost of implementing the intervention. In addition, the intervention was reported to be 17% more cost effective in Mozambique; but the cost per vaccine dose increased from US\$0.009 to US\$0.16 in Benin.

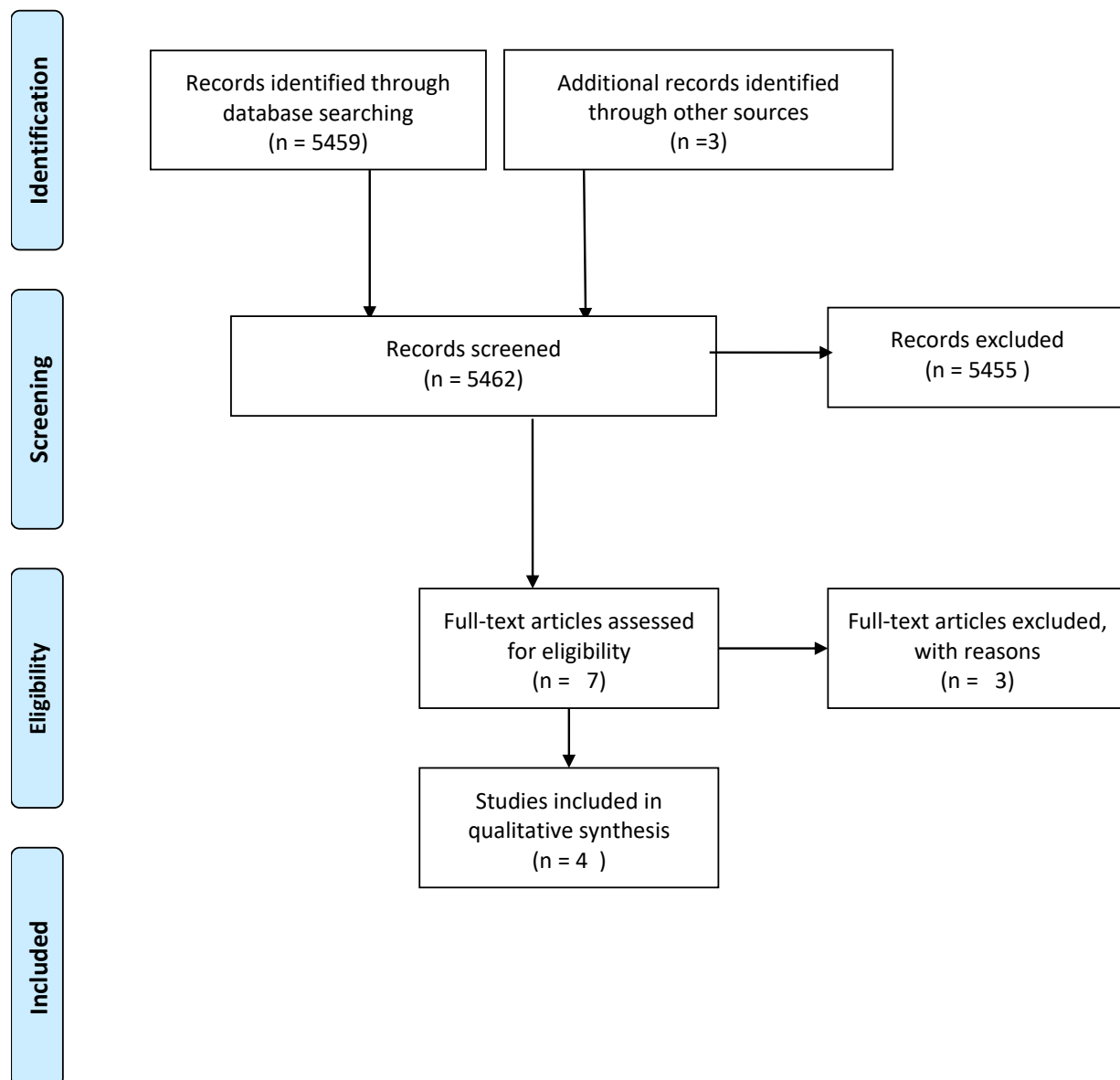
The third before-after study by Ramnujapuram and Akkihal<sup>27</sup> was conducted in 29 primary healthcare centers in Karnataka in India<sup>27</sup>. This study assessed the use of “digital bulletin boards”<sup>27</sup> by health facility managers who oversee the placing of new orders for vaccines. Vaccine stock levels, derived from real time data generated from primary healthcare facilities, were displayed on Television screens strategically positioned in managers’ offices or in places that are visible to them, to prompt them into acting. The study reported a steady improvement in vaccine availability up to 99%, though the baseline score was not mentioned. There was also a reduction in replenishment time from 14 to 5 days<sup>27</sup>.

The fourth study, a randomised trial by Pereira et al<sup>28</sup>, assessed the effect of using barcode scanning technology for vaccine record compared to the manual entry of vaccine records. The barcode method involved scanning the barcode on each vaccine vial such that all the information of the vaccine (such as lot number and expiry date) is captured in an electronic data recording system. The other approach involved manually entering all the vaccine information into a predesigned drop-down menu on the computer system<sup>28</sup>. This study measured the completeness and accuracy of data entry. The study observed fewer errors when using barcode scanning, although the exact values were not reported<sup>28</sup>.

All included studies<sup>4,26–28</sup> were judged to have high risk of bias since they scored high at least in one of the three domains, that is, completeness of outcome data, similarity of baseline characteristics, and similarity of outcome characteristics. The summary of our risk of bias assessment is shown in Table 2.

**Table 1:** List of excluded studies with reasons

<b>Study</b>	<b>Study design</b>	<b>Reasons for exclusion</b>
Shieshia 2014 <sup>29</sup>	Before-after study	The study assessed the effectiveness of an SMS and web-based reporting system used to report stock data using SMS through mobile phones. We excluded this study because its focus was on health products and did not specifically mention vaccines
Kapuria 2014 <sup>30</sup>	Before-after study	The study assessed implementation of vaccine logistic management system which enables the visibility of stock levels in real time coupled with strengthening of human resources capacity. We excluded this study because at the time of assessing the article, results of the study were not out yet
Brown 2014 <sup>21</sup>	Modeling study	This study assessed the effects of redesigning the vaccine supply chain. However, the authors conducted the study using computational modeling, a basis for exclusion in this review



**Figure 1: Process of study selection for the scoping review on interventions for vaccine stock management**



**Table 2:** Risk of bias assesment for included studies

Domain	Gilbert 2017	Prosser 2017	Ramanujapuram 2014	Pereira 2012
Random sequence generation	⊖	⊖	⊖	⊕
Allocation concealment	⊖	⊖	⊖	?
Baseline outcome measurements similar	⊖	?	⊖	?
Baseline characteristics similar	⊖	⊖	?	⊖
Incomplete outcome data (attrition bias)	?	?	?	?
Knowledge of the allocated interventions adequately prevented during the study	?	?	?	?
Protection against contamination	⊕	⊕	⊕	⊕
Selective reporting (reporting bias)	?	?	?	?
Other bias	?	?	?	?

**Key:** ⊕ Low risk of bias; ⊖ High risk of bias; ? Unclear risk of bias

#### 4.4. Discussion

The rise in occurrence of stock-outs suggests a need to improve vaccine stock management in countries, especially low- and middle-income countries<sup>15</sup>. We conducted a scoping review to evaluate the effects of interventions for improving vaccine stock management.

Our comprehensive literature search identified a total of 5 462 records, out of which four which were found eligible for inclusion. Three of these studies were before-after studies conducted in low- and middle-income countries and one was a randomized trial conducted in a high-income country. The first study <sup>4</sup> showed that the use of a combination of interventions including use standard data collection instruments, digital tools, training of health care workers, and assigning specific roles to personnel, can increase vaccine availability and reduce replenishment time. The second study showed that redesigning a supply chain from a four-level system to a three-level system can improve vaccine availability and reduce stock-outs <sup>26</sup>. The redesigned process reduces the complexity of getting vaccines from the highest level in the supply chain to health facilities. This process resulted in an informed push system, in which vaccines are supplied from the higher levels of the supply chain to the health facilities, which is often informed by the level of consumption in these facilities. The findings from this study is consistent with another study conducted in Senegal, where introducing an informed push system reduced the rate of stock outs of contraceptives <sup>32</sup>.

The third study <sup>27</sup> showed that the use of screens to display abnormal stock levels to vaccine managers not only improves vaccine availability but can also reduce replenishment time. The fourth study showed that integrating barcode scanning on vaccine vials as opposed to manual method or drop-down menu to record vaccine inventory could reduce errors that occur when inventory data are captured.

Most of the interventions described were effective in LIMICs <sup>4,26,27</sup> implying that they are likely be effective in similar settings, especially hard to reach areas.

Three studies <sup>4,27,28</sup> in this review included a component of digital technology, to improve visibility of vaccine stock levels. Many countries have also adopted the use of digital systems to monitor vaccine levels, making them visible for managers to make informed decisions. Countries such as India, Mozambique, and Nigeria use these systems to improve vaccine

availability<sup>18</sup>. South Africa for example, has developed the "Stock Visibility Solution" which is a mobile application designed to enable health facilities to monitor and capture stock levels daily. The information is stored in a cloud-based data management system and can send alerts when the stock is running low<sup>33</sup>. The use of digital technologies as interventions for stock management have advantages over manual methods and should be embraced by LMICs as they have the potential to strengthen health systems<sup>34,35</sup>. Furthermore, data from manual stock records are not usually efficient to support decision making, due to poor data quality, wrong estimates of vaccine consumption and late arrival of data at managerial levels<sup>36</sup>. Manual reporting systems are also labour intensive and tend to overburden healthcare workers. This in turn affects the motivation of healthcare workers who may end up resenting the responsibilities of vaccine stock management because they often also have other duties including clinical duties<sup>9,36</sup>. When adequate data are not available, it affects the placing orders and could lead to shortages<sup>35</sup>. In addition, findings from this review have underscored the importance of assigning a specific person at health facility level to manage vaccine stock, as highlighted in the studies by Gilbert et al<sup>4</sup> and Prosser et al<sup>26</sup>.

Current evidence shows that the use of digital solutions are effective for solving public health problems, but the ones that target the vaccine supply chain are still scarce<sup>36,37</sup>. To the best of our knowledge, this study is the first to assess the effects of interventions for vaccine stock management in health facilities where vaccines are administered.

One of the limitations to this study is that most studies included in this review had high risk of bias mostly due to how they were designed and conducted. Also, the related outcomes in all studies were measured differently; there were no consistent methods for measuring outcomes such as stock-out rates and vaccine availability. Thirdly, our study focused only on interventions for vaccine stock management, so we had to exclude studies that reported interventions for other health commodities which could be very useful for vaccine stock management.

#### **4.5. Conclusion**

Interventions such as the use of digital information systems (e.g., use of mobile devices, display screens and barcode scanning of vaccines for recording); training of workers; assigning specific roles to specific personnel and redesign of the supply chain, have the potential to improve vaccine stock management which eventually can increase vaccine availability. However, well designed studies are urgently required to increase the certainty of the current evidence base.

## **Acknowledgement**

We are grateful to Elizabeth Pienaar for assisting in developing the search strategy.

## **Authors' contributions**

The study was conceived by CJI and CSW. CJI and AJ were involved in screening of articles for eligibility and data extraction. All authors contributed to the analysis of the data. CJI drafted the review while AJ, CSW, LM and NN made additions where necessary, reviewed the layout the meaning and interpretation of results. All authors contributed to the final draft and approved the final version of the manuscript.

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## CHAPTER FIVE

### Mobile reporting of vaccine stock levels in primary health care facilities in the Eastern Cape Province of South Africa: perceptions and experiences of health care workers

This manuscript has been submitted to *South African Medical Journal*

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## 5.0. Abstract

**Introduction:** The use of mobile and wireless digital technologies - mobile health (mhealth)- is increasingly been adopted in low- and middle-income countries (LMICs) to improve data visibility, improve decision-making, and consequently help ensure availability of health commodities in health facilities. In a bid to improve availability of medicines in primary health care facilities, the South African department of Health launched the Stock Visibility Solution (SVS), a mobile application developed for the purpose of capturing and monitoring stock levels of medicines including vaccines using mobile phones. The stock levels of medicines in facilities are usually uploaded to the central stock management system so that managers can act promptly to address stock-out situations. Pilot studies show that the SVS has the potential to reduce stock-outs from occurring. This study aimed to explore the perceptions and experiences of the SVS system amongst healthcare workers (HCWs) who are involved with managing stock levels of medicines in primary health care facilities in the Eastern Cape Province. This will help identify potential barriers and facilitators to implementation of the system and contribute to the development of strategies to improve its efficiency and effectiveness.

**Methods:** A qualitative research design was employed, including semi-structured interviews with 64 HCWs working in primary health care facilities in the OR Tambo district, Eastern Cape Province in South Africa. Data was transcribed verbatim and analysed using thematic analysis.

**Results:** Most HCWs understood the SVS as a system for reporting stock levels to managers and conveyed commitment to ensuring the system works. However, they highlighted a number of factors that demotivated efficient usage of the system: inadequate training, staff shortages and high staff turnover, lack of responses from the managers, the extra workload that comes with the system, amongst others. HCWs made various suggestions for how the system might be improved, most pertinently the need for more pharmacists and pharmacy assistants and for these cadres to be primarily in-charge of stock management and the use of the SVS.

**Conclusion:** While HCWs are committed to addressing vaccine stock-outs, they face various barriers to an effective and efficient implementation of the SVS system. We make various recommendations for how these barriers might be addressed.

**Keywords:** Stock visibility solution, supply chain, mhealth, digital health, mhealth, South Africa

## 5.1. Introduction

The use of mobile and wireless digital devices to improve access to healthcare information (mhealth), is increasingly been adopted in low and middle-income countries (LMICs).<sup>1,2</sup> These devices are being used to improve data visibility, enhance decision-making, and consequently help ensure availability of medicines in health facilities<sup>3,4</sup>. The use of these mobile devices has the potential to tackle the challenges of stock-outs of vaccines and other health commodities in health settings.<sup>1,2</sup>, especially in rural and resource-constrained areas<sup>2</sup>.

Vaccine stock-outs at primary healthcare facilities is one of the challenges facing the immunisation programme the health of the people of South Africa.<sup>5,6</sup> Vaccine stock-outs and child deaths due to vaccine-preventable diseases are common in rural communities which are sometimes hard to reach.<sup>7</sup> South Africa has made significant progress with the introduction and self-financing of new and underutilised vaccines. However, there have been reports that point to shortages of vaccines in many parts of the country<sup>8,9</sup>. In a bid to reduce the rate of stock of stock-outs of medicines, the department of health in South Africa developed the 'stock visibility solution' (SVS), the South African department of health, launched a mobile application, the stock visibility system (SVS) for monitoring the availability of medicines in primary health facilities level.<sup>10-12</sup> The SVS is designed to capture vaccine stocks through mobile phones.<sup>13</sup> At the health facilities, the health worker in charge of stock management by reporting vaccine stock levels and other medicines to managers at district, provincial, and national levels. Stock reporting is expected to be done weekly by the staff in charge. During this time, the quantity of each stock item is counted, updated on the device and sent. The data is automatically uploaded to an online stock management system, whereby all managers can access the stock-levels of all the facilities in real-time. This central stock management system can detect stock-outs reported at the facilities, including details of the item and duration of stock-out. Warning signals are then sent to the managers prompting them to respond.

In most cases, it is sub-district managers or other persons who are responsible for overseeing facilities within their region that respond.<sup>10,13</sup> When the managers receive the reports, they are meant to call facilities with low stock levels to confirm whether the item has been ordered from the depot. The manager can also attempt to source the item from other facilities where it is in stock. This stock redistribution helps to ensure that medicines are always available in the facilities and patients are not turned away due to stock-outs.

Pilot studies conducted in Kwazulu-Natal and Limpopo<sup>14</sup> provinces in the country showed that the SVS is capable of reducing stock-outs of medicines in primary health care settings<sup>15</sup>. However, it is known that the success of a technological intervention such as the SVS will be impacted by the human element<sup>10</sup>, including the staff at the facilities as well as the managers. The aim of this study was therefore to explore the perceptions and experiences of the SVS system amongst healthcare workers (HCWs) who are involved with managing stock levels of medicines in primary health care facilities in the Eastern Cape Province. This will help identify potential barriers and facilitators to implementation of the system and contribute to the development of strategies to improve its efficiency and effectiveness.

## **5.2. Methods**

### **5.2.1. Study setting:**

Our study was conducted in the OR Tambo district in the Eastern Cape Province of South Africa. The OR Tambo district is the largest district in the Province with a population of 1,382,399, which is 20% of the population of Eastern Cape Province.<sup>16</sup> It is a rural district comprising of four sub-districts- Nyandeni, KSD, Mthlontlo and Quakeni. The district was chosen as one of the National Health Insurance (NHI) pilot districts in South Africa, where various initiatives have been implemented to improve the quality of care. Some of these initiatives include the e-health strategy, supply chain management reforms, amongst others. The OR Tambo district also has high neonatal and child mortality, coupled with a high burden of HIV/AIDS and TB epidemic.

### **5.2.2. Research design:**

We employed a qualitative research design, including semi-structured and in-depth interviews with HCWs in primary health care facilities across the four sub-districts of the OR Tambo district. This study forms part of a broader, quantitative study which is assessing the occurrence of vaccine stock-outs and vaccine stock management status of the health facilities within the OR Tambo district.

### **5.2.3. Sampling and recruitment**

We employed a purposive sampling approach. For the broader, quantitative study, we visited facilities across the four sub-districts to capture data related to vaccine stock management. While visiting the facilities, we used the opportunity to conduct interviews with HCWs who are involved with capturing, monitoring and reporting stock levels of medicines. These HCWs were

pharmacists, pharmacy assistants and nurses. On the days we visited the health facilities, most of the people we approached were willing and happy to participate in the study despite their busy schedules.

#### **5.2.4. Data collection and management**

Individual interviews were conducted with participants between 25<sup>th</sup> February to 15<sup>th</sup> March 2019. The interviews were based on a semi-structured interview guide which explored the following topics: knowledge of the SVS, the impact of SVS on the occurrence of vaccine stock-outs challenges faced by the HCWs using SVS and the HCWs' recommendations to the challenges. (See Appendix 1). The guide was flexible to ensure that participants could express what was important to them, and so learnings from previous interviews could be clarified and probed further in subsequent interviews.

Before each interview, we explained to the participants the purpose of the study, sought for their consent and assured them of confidentiality. With the permission of participants, each session was recorded using a digital recorder. Also, notes of both verbal and non-verbal responses were taken during the interviews. Interviews were conducted at a convenient place chosen by each respondent. For example, interviews were conducted in the medicines storeroom or their offices. All interviews were conducted in English language and lasted between 30 and 60 minutes. All interviews went smoothly, and only one participant pulled out in the middle of the interview for health reasons.

At the end of the interviews, the recorded sessions were transcribed verbatim and saved in a passworded computer, in a file bearing the date the interview was conducted, the place where it was conducted, and the questions the interview addressed. Field assistants were employed to assist with the transcribing. However, each transcribed interview was verified by the principal investigator (CJI) to check for accuracy.

#### **5.2.5. Analytic process**

The transcribed data was analysed using thematic analysis.<sup>17</sup> Thematic analysis is a useful method for identifying and describing recurring patterns that are present in data <sup>17</sup>. Three authors (CJI, LM and SC) participated in the analysis. The analysis of these interviews began before data collection. We had meetings to deliberate and agreed on the analytic method to use based on the data that will be collected. Notes were made during the interviews and summaries were written after each interview to guide us through the analytical process. We shared the

transcripts amongst ourselves for independent coding and then met to agree on common codes and emerging themes. During this process, each author read the transcripts for adequate immersion in the data and notes were taken. We then developed themes which were used to code the data. We tested some of the identified themes against the interviews to be sure the information was well captured, bearing in mind the aims and objectives of the study.

#### **5.2.6. Ethical consideration**

Ethics approval was obtained from the Health Research Ethics Committee, Stellenbosch University (S18/08/154), the provincial department of health (EC\_201810\_009) and the OR Tambo district. All participants were assured of anonymity during the interviews. A consent form was provided to each interviewee before the onset of the interview. In the consent form, it was clearly stated that the interview would be recorded, and the discussion with the participants will be kept confidential. The participants were also informed verbally about how their confidentiality will be kept and that they are free to withdraw from the interview at any time. The data collected was kept safe and protected. Also, identifiers were removed from transcripts, and sound files were destroyed after the interviews were transcribed.

### **5.3. Results**

A total of 64 participants were interviewed, from all the sub-districts within the OR Tambo district; 23 from Nyandeni 21 from KSD, 13 from Mthlontlo and seven from Quakeni. Each participant represented each of the 64 facilities. Table 1 below contains a list of respondents.

#### **Summary of themes generated from study**

Six main themes were derived from the data namely; knowledge of the purpose and functioning of the SVS system; frustration about the ineffectiveness of the SVS system; challenges encountered when using the SVS, (with its sub-themes), novel alternatives to the SVS system. Finally, a theme on recommendations made by the HCWS, for addressing identified challenges. The sub-themes that emerged from the challenges encountered by the HCWs include staff shortages and high staff turnover, inadequate training of HCWs, lack of response from the managers, increased workload, SVS reporting being time consuming, the inability of HCWs to meet up with sending reports. The major themes are written in bold, while minor themes are italicised in bold. Each of the themes is described below.

**Table 1: Profile of respondents**

Sub-district	Pharmacist	Pharmacy assistant	Vaccinator	Facility manager
King Sabata Dalindyebo	1	6	12	2
Nyandeni	0	9	8	6
Quakeni	0	4	1	2
Mthlontlo	1	5	4	3
All facilities	2	24	25	13

### 5.3.1. Widespread knowledge of the purpose and functioning of the SVS system

Most of the HCWs we spoke to conveyed considerable knowledge about the SVS, including its purpose and how it functions. Most participants described the SVS as a tool used for reporting the stock levels of vaccines and other medicines. Some even highlighted details the categories of medicines that are reported using the SVS, namely; vaccines, antiretrovirals, anti-tuberculosis (TB) drugs, and other tracer medicines:

*“with I SVS ke, we’ve got a phone here to where we were being asked about the TB drugs the vaccines, ARV, TB, the vaccines back since, we... we..., with the I SVS we have to balance first the Medication and before you sent to you balance first in the medications and you... you send according to the balance of the bin cards yes and we do it on Tuesdays, if not done on Tuesday then early on”(HF5).*

Many of the HCWs we spoke to also knew that the SVS helps to monitor stock availability and expiry dates of medicines, in addition to using the SVS to report medications:

*“..with vaccines we are able to check how many do we have at the moment, which one is about to expire and trying to get finished so if they’re short we are able to place a special order, so it reminds us if we haven’t placed an order it will say place an order for that because its running short” (HF1).*

They also described the SVS as a system that enables them to redistribute stock levels as well as a reminder for when stock levels are running low:



*“Yes, definitely maybe there is somebody who is looking at the stock levels but the way I understood it is that we will share this stock” (HF35).*

*“I thought that with SVS, those facilities who have enough stock or access will transfer to us” (HF11).*

*“so if they’re short we are able to place a special order, so it reminds us if we haven’t placed an order it will say place an order for that because its running short” (HF18).*

### **5.3.2. Frustration about the ineffectiveness of the SVS system**

We asked participants directly whether they felt the SVS had been an effective system in reducing stock-outs since it was introduced. Here, the overwhelming majority of the HCWs we spoke to felt the system had been ineffective. The widespread perception was that stock-levels had remained more or less the same since its introduction:

*“there is no difference, without this SVS and with SVS, no difference. I am saying so because we were having the problem with the immunisations before and even now we still have the same problem so no difference, so you we just like, we just send the stock numbers weekly, but we don't know what is happening” (HF46).*

Another participant expressed similar sentiments:

*“It is not helping at all, we are suffering my dear, we are suffering here at the communities, maybe SVS is working in the suburbs, but here it is not working at all, in our areas, it is not working” (HF28).*

Some of the participants exhibited uncertainties, whether it has an impact or not:

*“I cannot say if it is decreasing or increasing,”. the point is that, let's see what I've just talked to you that when you are in the dispensary, and you always see that something's out of stock, you think of it even before SVS and you make a way of getting that drug” but then SVS has helped us a lot because now we always have to update (HF17).…”*

*“otherwise, it is a reliable model; it' is fine, but I do not know as to we are the ones who are failing as nurses to share the stock amongst ourselves (HF54)..”*

The ineffectiveness of the system appears to be a source of considerable frustration for many of the participants we spoke. However, we were indeed struck by the level of commitment many of the staff appear to have, and their wish to ensure that vaccines are available.

*“it is very bad to always not have when the client comes to not have this drug” (HF5).*

*“..because it is not nice to tell the patient we don't have that go and ask somewhere..”(H18).*

*“..... that is not for the patient, it is for me to make sure that the treatment we have but at least” (HF54).*

One participant recounted that they had to travel to other facilities to pick up vaccines. Another said that if she had to refer them to other facilities, she would ask the patients to return to the clinics to show proof that they had received the vaccines.

Ultimately, the ineffectiveness of the system was perceived by some of the HCWs as demotivating, as expressed by this participant:

*“People are not motivated to report because we do not see the results” (HF25).*

### **5.3.3. Challenges to effective SVS implementation**

#### **Lack of training on the use of the SVS and adaptation**

When the participants were asked if they had received any formal training on how to use the SVS device, most of them expressed that they had not been well trained. Knowledge was mostly passed down to them from their operational managers. In some cases, they were taught by their predecessors or colleagues. Many of them did not find this style of training useful, and hence, adaptation to the tool was a bit challenging:

*“Noo, only our OM (operational manager), she was trained. Yes, she was trained, and she came to train us” (HF16).*

*“so, another one just phones you there and ask, hey how is the SVS thing going, ok. You see. You just go to the phone. You tick what and you click there then you do you your stock, and then you do what... so you see, that is not a training?” (HF60).*

#### **5.3.4. Staff shortages and high staff turnover**

Also, there is understandably, a frequent migration of health workers in this region. That is, the health workers, especially the pharmacy assistants are not stable. The next person who comes after may not be able to operate the system.

*“our challenges are adapting. At times we are having a new staff so like I say now the one who was doing ilanto I medication she has just left for the study leave so I SVS is easy when you*

*know it but if you do not know it you feel like it is a difficult thing but when you are used to it is not that difficult. You must be used to it" (HF35).*

### **5.3.5. Lack of responses from the managers**

Most participants recounted how lack of response from the managers is a huge challenge to the implementation of the SVS. They try to meet up with their reporting hoping that their managers will respond to the stock-out situations:

*"I really don't know because you are the first person who is asking me that question. I thought our pharmacist would be active enough to phone and check do you have enough of this in this because maybe another clinic has got so much, so that is what I was expecting" (HF44).*

*"We just send the stock numbers weekly, but we do not know what is happening" (HF38).*

### **5.3.6. SVS contributing to heavy workload amongst the HCWs**

Firstly, most of the participants felt that the SVS poses as an extra burden for them, especially as there are a lot of medicines on the system to be reported weekly:

*"So, there are so many programs and it does make it difficult even now I'm alone so you see" (HF10).*

*"Ok, Uhm, we do not only put immunisations ones only, there are other medicines from this, like TB medicines, everything in here, so it is too much, sooo... yaa, before it was only immunisations, ARVs, TB medicine soo...but now everything. So, it was fine when it was only immunisations, ARVs, and TB" (HF19).*

### **5.3.7. Reporting with the SVS is time-consuming**

Secondly, the participants felt that sending of reports is time-consuming. They spend much time capturing each item and sometimes stay beyond work hours in order to meet up with the days set for reporting weekly:

*"it's time, we don't have time" (HF34).*

*"yah so I have to stay back at half past 4 and do it and complete it" (HF37).*

*"so we've got a lot of work , we are few at the clinic so at times I do stay here when others knock off at half-past 4 and do the SVS, yes because of I shortage of staff " (HF28).*

### 5.3.8. Failure to send their reports

Furthermore, due to their busy schedules, they sometimes fail or delay in sending their reports.

*“But sometimes we do not enter the medicines that we are supposed to enter, because we will be busy. At times we do not have time to do this really well, we need someone on our service” (HF35).*

*“yah we have to order and sometimes our orders go late because we are busy, and when you order you do not need one day ” (HF62).*

### 5.3.9. Novel alternatives to the SVS system?

As described earlier, the HCWs conveyed a high level of commitment to ensuring that vaccines are available for patients. This was revealed further by the descriptions various participants gave about the strategies they developed to facilitate sharing of vaccines among themselves. One of these strategies was the creation of online groups on ‘WhatsApp’. On the ‘Whatsapp groups, when one facility needs an item, the HCW in charge of that facility creates a post requesting if another facility could assist. Since other facilities have access to this group, whoever is willing to share, responds to the request. They also use their mobile phones to call neighbouring facilities and, in some cases, use their cars to pick up these items from other facilities. Driving to borrow vaccines from other facilities, besides being daunting also has financial implications:

*“yes, my dear, even with the WhatsApp thing, we are using our own data to rotate the medication, there is a group here, pharmaceutical group, but it's not helping us...we use our own data, but somebody there is using official data, if there is an official data, I'm sure there is. Because even the cell phone is official, but here we are using our own data” (HF10).*

However, many participants expressed displeasure in using their personal resources for health service delivery, and felt that these novel strategies require more official support:

*“So, it's like you have to do this using your own transport and what are they going to say, they are going to say, we do not replace for the transport(HF15).*

### 5.3.10. Recommendations for addressing identified challenges

Participants provided two main suggestions for how the challenges they identified might be addressed. Firstly, most participants suggested that there should be pharmacists or pharmacy assistant in each facility who will be in charge of managing vaccines and of course, other

medicines in general. They felt that having a dedicated staff for these purposes will enable other staff like the nurses to focus their attention on their primary duties.

*“They must help with a Pharmacy assistant; we are nurses not pharmacy assistants” (HF5).*

*“there should be pharmacist., to do all the work for ‘I medication’(the medications)” (HF8).*

“So, the main issue is getting someone if these, if all the medicines will remain on the device, then they must get somebody that will manage” (HF15).

*“so it helps a lot but if we can have a pharmacist is will real help a lot. because now you are doing this and then this one of the sisters will come and say we do not have this we have to stop doing your admin and then to concentrate on this and phone all these clinics to find out do you have this” (HF18).*

*“mm, yes, Pharmacy assistant, it would be nice, Because we have to, we see the patient and then you have dispense for them And then I have to do my admin and I have to order the medication, there are things, like this stuff and HR things that I have to attend the meetings, I can say to my manager, no I have to do pharmacy things when she when there's a meeting. So, “I have to be at all places, you understand. So, if at least we can have a pharmacist I will be pleased” (HF5).*

Secondly, many participants suggested that their managers at the sub-district and even district levels should endeavour and respond promptly and offer support to them, especially regarding the redistribution of stocks between facilities. Even if there are no vaccines available, they still would like to receive feedback from the managers to show that they are aware of the situations in the facilities.

*“I think we have to involve all facilities in sub-district and then the district, we have to support each other, we are not being supported by our superiors” (HF16).*

*“If our supervisors can be involved at least it can help, move a little faster but it is not working, it's slow” (HF18).*

*“what I think can be done is for whoever is receiving the information can check as to who is out of stock not necessarily on weekly basis if she checks once because at the end we are also waiting for our stocks from the depot as I said we are ordering every month because of unreliability of our storage and electricity, ; yes, because if you phone us, and we are supposed to receive stock today, and we have the circle, the SVS circle yesterday and he looks today and see that we don't have for example BCG and other meds and then he sends to the health centres, or the other clinics that are close to us, if they have let's say 50, at least 10 for a week then it is shared amongst us if he phones and we say we have not received stock then a facility can send us 10 and when we receive the 50 then we send it back to the clinic” (HF25).*

Thirdly, the HCWs suggested that the bin cards be phased out. In these facilities, the bin cards have been used for a long time for recording stock levels of vaccines, and also other information like name of the vaccine, quantity, vial size, expiry dates and others. The bin cards are meant to help them monitor their stock levels in the facilities. While the information on the bin cards which is supposed to match with the physical quantities are also recorded on the SVS and sent to the managers, who can see the stock levels in the facilities. The HCWs would prefer to work only with the electronic device and not both. Updating both the stock cards, and the SVS is really much work to do, considering that they have to attend to their patients:

*“I would be happy if they would do away with the bin cards” (HF10)*

Lastly, they would also want to have access to the data on stock levels of other facilities so that they can know which facility to call when they are in need. Although this is meant to be done by the managers themselves.

*“If they can give everyone access to other facilities' information... If it can also show the stock visibility at the depot” (HF10).*

#### 5.4. Discussion

In this study, we have explored how HCWs involved with stock management in primary health care facilities in the OR Tambo district perceive and experience the use of the SVS for monitoring and reporting vaccine stock levels.

The HCWs are extremely knowledgeable about the purpose of SVS and how it works. They understand that it is meant to assist them in monitoring the stock levels of vaccines in the facilities, prompts them when stock is about to expire and mostly how it is used for reporting stock levels to the managers. They also do acknowledge that the system was created to help them reduce the level of stock-outs that occur in the facilities. Since they are meant to report every week, most of the participants reported that they hardly missed the chance to submit their reports. Also, they are extremely motivated to reduce stock-outs and its impact on the patients.

Despite the commitment to consistent reporting using the SVS, they are concerned and frustrated that the SVS system is currently ineffective. They identified all sorts of challenges contributing to its effectiveness. Firstly, the lack of response from the managers. Ideally, when the managers receive the reports, they are expected to respond to the facilities with low stocks of vaccines, by assisting in redistributing vaccines between facilities. The reasons for the lack of response from the managers is not clear in this study as we could not interview them. However, this lack of response from the managers may be due to failure on their part to monitor stock levels of medicines in the facilities assigned to them. Also, one may want to ask questions around the exact format in which these reports are received on the managers' side. In other words, how do these managers make sense of these reports received from the facilities? Are they properly trained? Also, do they face similar challenges as the staff in the facilities where they may be overburdened and may not be able to respond promptly? Getting answers to these questions may assist in understanding the reasons for the lack of response from them.

Furthermore, the lack of support from managers is a factor responsible for low motivation amongst health workers in developing countries. This was shown in a systematic review where the majority of studies (85%) reported that lack of support or proper supervisory roles from the superiors de-motivated the health workers<sup>18</sup>. Also, the availability of health commodities has been identified in the same review<sup>18</sup> and another study<sup>19</sup>, as one of the motivating factors for health workers, while the lack thereof, can be a strong demotivating factor<sup>18</sup>. The recurring stock-outs of vaccines probably explains the frustration felt by the participants in this study.

Another demotivating factor identified from this study is that the health workers felt that the SVS is an extra burden on them, considering that they have other primary health care services to deliver. Mounting workload, in rural facilities, is a factor responsible for low motivation among health workers.<sup>19</sup> The extra burden that is being experienced from using the SVS, the delay in receiving responses from the managers, delay in receiving orders from the depot, and the urgent need to send reports of stock levels of vaccines and other medicines every week, could explain the frustration and anxiety among these health care workers.

The HCWS are also developing novel, ground-up alternative strategies for managing and reducing stock-outs. They use their phones to make calls; they formed 'WhatsApp' groups where they share items and sometimes use their vehicles to fetch vaccines from neighbouring facilities. Situations, where health workers use their personal resources to assist in health care delivery, are common in developing countries and have been reported in other studies.<sup>20,21</sup> Some studies have also shown that health workers use online communities like WhatsApp' 'Facebook' to respond to stock-outs and to share knowledge among themselves.<sup>2,20</sup> The use of alternative strategies holds great potential for the development of interventions which are contextually appropriate and acceptable to those who are tasked with managing stocks. However, if these are to be harnessed, they need support.

## **5.5. Recommendations**

Staff shortages as reported by the participants in this study have been shown to be among the challenges of the health system the OR Tambo district<sup>16</sup> and other low and middle-income settings, especially the rural areas.<sup>2,19</sup> If this problem is not tackled, the realisation of the full impact of interventions like the SVS may be threatened.<sup>19</sup> It is, therefore, an important for policymakers to seek ways of addressing staff shortages at the health facilities and the sub-district levels. Health workers need to have the right emotions towards their work as low motivation has an undesirable impact on the performance of individual health workers, facilities and the entire health system. It could also contribute to the migration of health workers from rural areas to the cities.<sup>19</sup>

Finally, if the managers are too busy to look at the reports sent from the facilities, then there may be a need to adopt specific strategies to prompt them into responding on time. For example, a study conducted in India reported that digital screens were mounted at strategic positions on the offices of the managers<sup>22</sup>. These screens were meant to project only abnormal



levels of medicines such that the managers can quickly identify facilities who need help and assist them without necessarily checking their systems.

### **5.6. Study limitation**

Not being able to interview the managers at the sub-district and district levels was a limitation to this study. Their voices would have provided a balanced view of the study.

### **5.7. Conclusion**

The SVS has the potential to minimise the occurrence of stock-outs of vaccines and other health commodities in the health facilities. However, it may contribute to the extra workload being experienced by health workers in rural areas, coupled with the current shortage of staff. There is a strong commitment on the side of health workers, ensuring that vaccines and other health commodities are continuously available for their clients. However, their zeal is reduced by the unavailability of health commodities at the facilities, delay in deliveries from the depot, and the slow response from the managers. There is a need for policymakers to seek ways of addressing stock-outs, addressing issues around the health workforce and providing adequate training for the health workers.

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## CHAPTER SIX

### Discussion and conclusion

#### 6.1. Introduction

The availability of health commodities at the point of services is a fundamental component of the health system and also crucial for achieving universal health coverage (UHC).<sup>1,2</sup> Stock-outs of essential health commodities such as vaccines is still a challenge, particularly in resource-constrained settings. Vaccine stock management is a critical aspect of the supply chain that ensures that vaccines are always available at point of care.<sup>3-5</sup> Stock-outs of vaccines in health facilities have been linked to poor stock management.

This study aimed to evaluate the management and availability of vaccines in primary health care facilities in OR Tambo district, Eastern Cape Province. As part of the background to the study, a systematic review of both published and grey literature was conducted to provide evidence on the magnitude of vaccine stock-outs in the WHO African region. The evidence gathered from this review captured occurrence of vaccine stock-outs at different levels of the supply chain; the national, district and the health facilities and a link between the stock-outs that occur at the higher levels and those of the lowest levels. The causative factors of vaccine stock-outs at health facilities, which is the primary interest of this study were identified from the review. Poor vaccine stock management was found to be one of the major causative factors for vaccine stock-outs in health facilities, especially in low-and-middle-income countries.

This chapter provides an overview of the key findings and reflections on each objective of this study. Also, this chapter will describe the key findings, contribution to knowledge, implications for policy, study limitations, conclusions and future research.

#### 6.2. Key findings

##### 6.2.1. Vaccine stock-outs in Africa

This study revealed that significant stock-outs still occur at national and district levels in countries within the WHO African region, with a direct impact on the delivery of immunisation services. The vaccines most affected are BCG and oral polio vaccine.

When stock-outs occur at higher levels in the supply chain, there is a high chance that the lower levels will be affected. Findings from this study also highlighted the considerable gap that exists in the reports of stock-outs at the health facility level, the most critical level in the supply chain as it has a direct impact on service delivery and ultimately on the population served. The study also revealed that many countries do not have systems for routine monitoring of vaccine stock-outs. South Africa is one of the few countries that seem to have a routine survey for stock-outs at the service delivery levels ongoing since 2013. Although the method used for the survey strongly underestimates the level of stock-outs occurring in the facilities. This routine survey revealed that stock-out rates could vary significantly between regions in a country, which is quite an important finding for health managers and policymakers.

Evidence from the literature review reveals that vaccine stock-outs in health facilities are mostly caused by poor stock management. Other factors that the literature review revealed include the introduction of new vaccines, lack of skilled personnel, disease outbreaks and an inadequate supply chain structure. Some of these factors were identified in the study in the Eastern Cape, such as lack of skilled personnel. The literature review findings were supported by the study conducted in the Eastern Cape, where there was poor vaccine stock management. There was also a lack of skilled personnel for vaccine stock management in the Eastern Cape. The nurses were mostly in charge of managing vaccine stocks and lacked the technical knowledge, especially regarding quantification of needs which is necessary for forecasting and ordering. This further complicated the situation where the supply chain structure is a pull system; the facilities are expected to place orders based on their needs.

### **6.2.2. Vaccine stock-outs and stock management in rural South Africa**

Our study, which assessed the occurrence of vaccine stock-outs, in OR Tambo district, showed that significant vaccine stock-outs occurred. Almost 80% of facilities reported a stock-out of at least one vaccine on the day of the visit. This is way higher than many countries and higher than the figures reported by the Stop Stock-out Project (SSP) in South Africa. This could mean that it is best to assess stock-outs with physical counts of items since other methods may underestimate the magnitude of the problem. Furthermore, vaccine stock-outs occurred regardless of the presence of pharmacy personnel; pharmacist or pharmacist's assistants. With these high rates of stock-outs, the emphasis by the department of health on "Everyday is an

Immunisation Day”<sup>6</sup> may not be achieved as some patients may be turned away due to lack of vaccines at the health facilities.

The assessment of vaccine stock management practices in OR Tambo district showed that the stock-cards are not used according to guidelines and expectations. Stock cards are still in use in all facilities, but the HCWs are reluctant to fill these cards. Failure to use stock cards and record all vaccine transactions on the stock cards as required, meant that stock cards could not be used for other critical functions such as estimating consumption rates. Many studies have also revealed that HCWs hardly update the stock cards.<sup>7-9</sup> It is therefore probably long overdue for the stock cards to be replaced with electronic stock management systems like the Px solution. The rapid global expansion of digital technology has emerged and provides an opportunity for mitigating the challenges of commodity distribution and stock-outs<sup>2</sup>. This might be an important opportunity for stock cards to be replaced by electronic stock management systems. An electronic management system should be able to perform all functions of the stock cards adequately. Where possible, a single system should be designed that can be used for stock management in the facilities and for reporting of stock levels to the managers at higher levels. Delays in the delivery of stock from the pharmaceutical depot also affected the supply of vaccines to the facilities. The lack of skilled personnel revealed in the study in the Eastern Cape corroborated the report from the literature review.

### **6.2.3. Interventions for improving vaccine stock management**

Our study in the Eastern Cape motivated the need to conduct a scoping review to identify interventions that could be used to improve vaccine stock management and increase vaccine availability. Most studies identified were conducted in low-and middle-income countries, and most of the studies reported the use of digital devices, to improve the quality of vaccine records and stock visibility. These interventions led to an increase in vaccine availability, improvement in accuracy of records and reduction in response times. The use of digital tools to improve stock visibility is like the stock visibility solution (SVS) system, which is being used in our study setting. The first study included in the scoping review, which was conducted by Gilbert et al.<sup>10</sup> incorporated three interventions targeted at the recording process and on the personnel managing vaccines.<sup>10</sup> The first intervention was the use of a standardised paper to capture stock utilisation which was then transferred into digital devices, such as mobile devices or computers(second intervention). The third intervention involved the use of dedicated personnel

at the district level to manage vaccine stocks. In the Eastern Cape, there are officials dedicated to receiving and acting on the reports from the SVS in the facilities.

The second study in the scoping review described how the redesign of the supply chain led to the improvement in vaccine stock management. This redesign process involved a reduction in the number of supply chain levels from a four-tier system to a three-tier system.<sup>11</sup> This system is most preferred as it has been shown that fewer levels in a supply chain improve vaccine availability through improved efficiency of the supply chain.<sup>11–17</sup> Interestingly, the Eastern Cape supply chain system operates on a three-tier system, where supplies are received by provincial from the national depot and supplied directly to the health facilities. In the study by Prosser et al.<sup>11</sup>, apart from the redesign of the supply chain, in Benin for example, a person was dedicated at the district level to collect vaccines from the regional stores, conduct monthly visits to the facilities for three purposes; vaccine distribution, collection of cold boxes, and supportive supervision. This dedicated person was also involved in analysing the data that was generated by the facilities for planning distribution. Refresher training was also conducted for health workers at the facilities. The interventions improved vaccine availability and reduced response time. Conducting refresher training in the Eastern Cape or generally, may be vital in improving vaccine stock management in primary health care facilities.

The third study in the scoping review describes the use of a digital tool, “bulletin board” to send the stock levels to the managers.<sup>18</sup> The ‘bulletin board’ was mounted on strategic positions that are easily visible to the managers. It was designed to project abnormal events such as stock-outs and excess stock to managers, thereby prompting them to take action. While the interventions described above have some similarities with the findings in the Eastern Cape province, this type of intervention was not identified in the OR Tambo study. The use of similar interventions may be useful in our study setting and beyond, where there is a lack of response from the managers. Figure 1 below shows a picture of the bulletin board and how it transmits information to the managers.





Figure 1: A typical Bulletin board that displays abnormal stock levels for the managers

Source: Ramanujapuram & Akkihal<sup>18</sup>



Figure 2: The events that are displayed to the managers by the 'Bulletin board'<sup>18</sup>

#### 6.2.4. The perceptions and experiences of HCWs with the SVS

The study on the experiences with and perceptions of the Stock Visibility system (SVS) by health care workers in OR Tambo district, found that most HCWs understood the function of the SVS, as a system for reporting stock levels to managers. However, potential barriers to efficient use of this device were noted. These factors include lack of response from managers, which was highlighted by a lot of the participants. Hence, they resorted to the use of "WhatsApp" to redistribute items between facilities. Such factor in other settings may have prompted the recommendation by WHO, that stock notifications should be used in settings where there is a timely response to stock-outs notifications.<sup>2</sup> Other potential barriers to the use of SVS in OR Tambo district include extra workload, staff shortages and occurrence of stock-outs despite the use of the SVS.

### **6.3. Contribution to knowledge**

This study contributes to the field of vaccinology, mainly supply chain management through the following ways:

- i. Information on the magnitude of vaccine stock-outs in primary health care facilities in OR Tambo District in the Eastern Cape.
- ii. The method used for assessing the stock-outs situation in the Eastern Cape province provided an actual situation as compared to other methods, such as the telephonic survey methods which most likely provides an underestimation of the occurrence of stock-outs in primary health care facilities.
- iii. Studies on the assessment of vaccine stock management practices in South Africa are very scarce. This study provided a comprehensive assessment of the vaccine stock management practices in the OR Tambo district of the Eastern Cape province, highlighting areas that require improvement which may be useful to the policymakers on EPI.
- iv. The scoping review highlights different approaches used by countries for stock management and reveals gaps for future research. For example, the scoping review revealed the need for well-designed studies that show the effectiveness of interventions to improve vaccine stock management.
- v. The systematic review on the occurrence of stock-outs revealed provided a comprehensive picture of the magnitude of stock-outs at the national, district and health facility level in the WHO African region.
- vi. The experiences of health care workers using the SVS, which revealed barriers to the efficiency of the system. This is a notable contribution to the body of knowledge, especially on the use of digital interventions to improve vaccine availability.

### **6.4. Implications for policy**

Most primary health care facilities are operated by nurses. Therefore, the nurses need to be trained and retrained at intervals on the management of pharmaceuticals and specific training on management of vaccines and such training should include specific qualities and requirements of vaccines, forecasting, management of cold chain and wastage. In addition to

training, the managers should always supervise and support health workers who are involved in stock management, to ensure they follow standard guidelines for stock management and to respond when their reports indicate that they lack vaccines. Sub-district managers should conduct regular visits to facilities and take action on the challenges they find.

There is a need to address human resources and pharmacy personnel issue and establish a standard if there is none in relation to the staffing of health facilities. It is also essential to review how the current situation fares in relation to such standard. If possible, more pharmacist's assistants should be employed so that they can be dedicated entirely to management of pharmaceuticals, and the nurses can focus on their primary duties in the facilities. There is a need for supportive supervision for effective adoption of the SVS. There is also a need for the use of electronic stock management systems in primary health care facilities. Such systems should integrate both stock monitoring and recording, stock reporting and possibly, immunisation coverage.

Policymakers should establish the minimum standard for health facilities and cold chain equipment they should have. Several facilities had limited cold chain capacity. Some facilities had other products like antiretrovirals, insulin, Rabies vaccine and some of the maternity drugs competing with vaccines for the minimal cold chain space. Policymakers should conduct a countrywide assessment of the cold chain and address this huge challenge for some facilities.

Health care workers have no clue on how to manage vaccine wastage, and there are no reports available on wastages. It is vital that this area is addressed and a clear programme should be directed at assessing the level of wastages and cost implications of all pharmaceuticals in all health facilities.

Finally, it is anticipated that the findings of this study will benefit policymakers as it provides crucial information for EPI programme on the current situation with vaccine stock availability and management in selected facilities in the Eastern Cape and on ways to improve vaccine stock management and to ensure availability of vaccines. The experiences of the HCWs on the use of SVS may help in further modifying the SVS as appropriate. Although the primary study is within the context of a rural district in the Eastern Cape Province of South Africa, it could serve as a guide for similar settings within South Africa and other countries.

### **6.5. Study limitations**

Our study was conducted in the OR Tambo District of the Eastern Cape. It may not be representative of the entire province but can give a snapshot of the situation in a resource-constrained area. Secondly, the magnitude of stock-outs from the Eastern Cape may be an underestimation considering that data was missing from facilities where stock-cards were not available. Finally, we could not reach the managers who receive the report on stock levels from the health facilities. Hence the experiences described in the study were mainly from the HCWs.

### **6.6. Conclusion**

Vaccine stock-outs is still a significant issue requiring urgent attention in the Eastern Cape Province of South Africa. They may have been caused by factors within the health facilities, such as poor vaccine stock management practices and factors outside the health facilities, such as delay in response time from the depot and lack of response from managers. This implies that poor vaccine stock management noted in the study facilities may be linked to a broader systems issue. There is a need for improvement in the areas highlighted in this study.

### **6.7. Future research**

The following studies may be important to undertake in the future:

- i. Exploring the experiences of the managers who receive Stock Visibility System reports from the facilities
- ii. Studies looking at interventions that for improving communication between the vaccine supply stores and health facilities
- iii. A study to assess the vaccine cold chain in primary health care facilities in OR Tambo District
- iv. A study to assess the level of vaccine wastage and its cost implications in primary health care settings

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## List of Appendices

### Appendix 1: Search strategy for a systematic review of vaccine stock-outs in primary health care facilities in Africa, for both PubMed and Scopus

	Query - terms / phrases entered	This column shows terms /phrases covered by what is entered
#5	Search #3 AND #4	
#4	Search "primary health care facilities" OR "Primary health care facility" OR "Primary health care clinic" OR "Primary health care clinics" OR "Health centers" OR "Health centre" OR "Health centres"	"primary health care facilities"[All Fields] OR "Primary health care facility"[All Fields] OR "Primary health care clinic"[All Fields] OR "Primary health care clinics"[All Fields] OR "Health centers"[All Fields] OR "Health centre"[All Fields] OR "Health centres"[All Fields]
#3	Search #1 OR #2	
#2	Search "Vaccine stockout" OR "Vaccine stock-out" "Vaccine unavailability" OR "Vaccine availability" OR "Vaccines stockout" OR "Vaccines stock-out" OR "vaccines unavailability" OR "Vaccines availability"	((("vaccines"[MeSH Terms] OR "vaccines"[All Fields] OR "vaccine"[All Fields]) AND stockout[All Fields]) OR ((("vaccines"[MeSH Terms] OR "vaccines"[All Fields] OR "vaccine"[All Fields]) AND stock-out[All Fields]) AND "Vaccine unavailability"[All Fields] OR "Vaccine availability"[All Fields] OR ((("vaccines"[MeSH Terms] OR "vaccines"[All Fields]) AND stockout[All Fields]) OR ((("vaccines"[MeSH Terms] OR "vaccines"[All Fields]) AND stock-out[All Fields]) OR ((("vaccines"[MeSH Terms] OR "vaccines"[All Fields]) AND unavailability[All Fields]) OR "Vaccines availability"[All Fields])

#1	Search "Vaccine stock management" OR "vaccine management"	((("vaccines"[MeSH Terms] OR "vaccines"[All Fields] OR "vaccine"[All Fields]) AND stock[All Fields] AND ("organization and administration"[MeSH Terms] OR ("organization"[All Fields] AND "administration"[All Fields]) OR "organization and administration"[All Fields] OR "management"[All Fields] OR "disease management"[MeSH Terms] OR ("disease"[All Fields] AND "management"[All Fields]) OR "disease management"[All Fields])) OR "vaccine management"[All Fields]
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## Appendix 2: The questionnaire for assessing vaccine stock management in OR Tambo district

Sub-District		Facility Name		Date and Time	
Position Respondent	Pharmacy Assistant	Vaccinator	Facility Manager	Other	
<b>A: General system and overview</b>					
No.	Question	Y	N	Comments Elaborate	
1	Is this an ideal clinic?				
2	Cold Chain Manual/ Vaccine Stock Management Guide available (from National DoH)			Indicate if verified: Yes or No.	
3	Eastern Cape DoH - SOP for Pharmaceuticals, Available?			Indicate if verified: Yes or No.	
4	What type of cold chain equipment is used?			1. Domestic Refrigerator/s 2. Vaccine Fridge/s: a. Upright Vaccine Fridges (minus 40) b. Chest like Vaccine fridge, Dometic. 3. Other: glass door fridges, etc.	
5.	Do you know temperature hold time of the fridge?				
6.	Do you have adequate fridge capacity?				
<b>B : Assessment of stock management procedures</b>					
7.	How is Vaccine Stock Managed? a. Manual Stock cards b. Computerised System c. SVS d. Other				
8.	What system/ form is used to order vaccines? a. Requisition form/book with carbon copy. b. Another form system Are records kept?				
9.	How often are vaccine <b>normal</b> orders placed. a. Monthly b. Every 2 months c. Weekly.				
10.	Are there delays in the delivery of stock?				

11.	If Yes – How long are these delays (commonly)? a. Delay by 1 week b. Delay by 2 to 3 weeks c. Delay by a month or more.			
12.	Are special emergency orders used?			
13.	How soon are emergency orders received? Are they helpful?			
	<b>Receiving stock:</b> Is there a special record of orders received other than stock card?			
14.	On stock arrival, Is there a standard procedure to check: Condition, Expiry date, VVM, etc.			
15.	Are these recorded and such records kept? If yes where?			Verify if Yes- where recorded.
	Are you familiar with FIFO/ FEFO principle?			Verify in fridge
	Is the FIFO/ FEFO principle applied?			
16.	<b>Stock Cards: Observe to Verify this information. Only indicate yes when verified</b>			
17.	Is the expiry date recorded on received stock?			
18.	Are batch numbers recorded on received stock?			
	Do you understand Maximum and Minimum levels?			
19.	Are Minimum levels on stock cards?			
	Are Maximum levels on stock cards?			
18.	Are they up to date/ filled regularly within 1 week?			
19.	Is there a stock card for measles diluent?			
20.	Do the measles doses match with diluent?			
	<b>Reduction of Orders and managing wastage</b>			
19.	Does the depot or the District Pharmacist reduce the quantities of orders placed?			
20.	Which vaccines do they frequently reduce?			
21.	Do you know the procedure to follow when vaccines are destroyed, expired?			
22.	What is it? Explain			
23.	Any disposed expired/wasted vaccines in last yr?			

24.	Are there records of disposed pharmaceuticals?			Verify if Yes- where recorded
25.	Do you know how to calculate vaccine wastage?			
26.	Are you expected to report on wastage?			
	<b>Stock Levels and stock out</b>			
	Are you currently out of stock of any vaccines?			
	Which vaccines are out of stock? Mention			
	How long have you been out of stock of above?			
	In the last year were you out of stock of vaccine?			
	Which ones ?			
	How long in average were these out of stock? a. On and off for over the year. b. Less than month. c. Over one moth			Elaborate
	<b>SVS system and Demonstration</b>			
	Is your SVS system working, currently?			
	Has someone been trained on it in this facility?			
	Have you had challenges with it? If yes what?			
	How often do you update and send data.			
	Has the SVS helped/ had a good impact in addressing shortages of vaccines.			Elaborate
	What can be improved with the SVS?			
	Are there other challenges with SVS?			
	<b>OBSERVATION: Fridge and Cooler Box</b>			
	Vaccines and Contents neatly packed.			
	FEFO Applied?			
	Is the temp chart a true reflection of fridge temp?			
	Are there Frozen vaccines?			
	If Yes which ones are frozen?			
	Do vaccines touch back plate with ice? Or ice accumulated in the fridge?			
	Are there Expired Vaccines?			
	Which vaccines are expired?			

	Are there opened vials of expired vaccines?			Indicating use of expired vaccines		
	Are there vaccines at VVM discard point?					
	Are vaccine doses and diluents equal or close?					
	Are vaccines in fridge door or vegetable drawer?					
<b>Fridge Stock</b>						
	<b>Vaccine</b>	<b>No.</b>	<b>Expiry Date</b>	<b>Expired</b>	<b>Overstock Y/N</b>	<b>Comments</b>
	BCG					
	Measles					
	Measles					
	Rota					
	PCV					
	Hexavalent					
	Polio					

### Observation of stock cards

Minimum= Y/N	Maximum = Y/N	Batch No.s = Y/N	Frequency use: Good= 4, Fair=3, Poor =2, V Bad=1	
		When received	Useful record: Good= 4, Fair=3, Poor =2, V Bad=1	
<b>Vaccine</b>	<b>Stock Level</b>	<b>Date Last Filled</b>	<b>Earliest Record Date</b>	<b>Zero levels in 2 yrs. Include duration</b>
BCG				
Measles				
Rotavirus				
PCV				
Hexavalent				
Polio				
<b>Notes</b>				

## **Appendix 3: Information sheet and consent form**

### **Information sheet**

*Each participant will be given a chance to read study information sheet*

Thank you for agreeing to take part in this study. Before I begin, I would like to explain why we would like to talk to you. This study is to find out about vaccine stock management and adherence to set standard practices for vaccine stock management. The study also aims to establish the situation with the occurrence of vaccine shortages, what causes shortages as well as the impact of the Stock visibility solution (SVS) on vaccine stock outs. We want to know whether the SVS tool that is being used makes a difference to ensuring vaccine availability. For the purposes of this interview, we would like to hear your views and experiences.

We want you to fill the questionnaire that will be provided to the best of your knowledge. At intervals, we may also do some physical checks in the vaccine store. We also want to hear your personal views and experiences. If you feel uncomfortable about answering any of the questions, you do not have to answer them. We will also request to review records on stock management including stock cards, computer records, ordering forms and similar related records. This study is for the purposes of research only and aims to contribute new information that can help improve vaccine availability and reduce stock-outs. This interview session will take 60 – 120 minutes including the physical checks.

Do you have any questions before we start? If not, you can ask a question at any time while answering the questions and at the end.

## Consent form for participants

Please complete this form in ball-point pen so that your writing can be seen on the bottom copy

1. I confirm that I have read and understood the information sheet dated .....for the above study. ☐
2. I have had the opportunity to think about the study and to ask questions about taking part. I am happy that my questions and concerns have been addressed. ☐
3. I understand that my participation is voluntary and I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐
4. I understand that this project has been reviewed and received ethics clearance by the Stellenbosch University of Ethics Committee ☐
5. I understand my personal details such as name, phone number and household will not be revealed to people outside the project. I understand that the information I provide may be archived by the project. I understand that the information I provide may be used in publications, reports, web pages, and other research outputs in an anonymised form. I understand that other researchers may have access to this data only in a securely anonymised form. ☐
6. I understand that if I have any concerns or complaints about the study, I can contact the Student's supervisor (Prof Charles Wiysonge) or the Chairperson of Stellenbosch University Human Research Ethics committee (who is not directly involved in this project). ☐
7. I agree to answer the questions. ☐

Name of participant:

Date:

Signature:

Name of Researcher:

Date:

Signature:

**Appendix 4: Ethics approval from Stellenbosch University, Eastern Cape department of health and OR Tambo district respectively**





**Health Research Ethics Committee (HREC)**

**Approval Notice**

**New Application**

11/10/2018

Project ID :7031

HREC Reference # S18/08/154 (PhD)

Title: Vaccine stock management procedures in primary health care settings

Dear Ms Chinwe Iwu

The Response to Modifications received on 01/10/2018 18:14 was reviewed by members of Health Research Ethics Committee via expedited review procedures on 11/10/2018 and was approved.

Please note the following information about your approved research protocol:

Protocol Approval Period: 11 October 2018 - 10 October 2019

Please remember to use your project ID (7031) and HREC reference number S18/08/154 on any documents or correspondence with the HREC concerning your research protocol.

Please note that the HREC has the prerogative and authority to ask further questions, seek additional information, require further modifications, or monitor the conduct of your research and the consent process.

**After Ethical Review**

Translation of the informed consent document(s) to the language(s) applicable to your study participants should now be submitted to the HREC.

Please note you can submit your progress report through the online ethics application process, available at: [Links Application Form Direct Link](#) and the application should be submitted to the HREC before the year has expired. Please see [Forms and Instructions](#) on our HREC website ([www.sun.ac.za/healthresearchethics](http://www.sun.ac.za/healthresearchethics)) for guidance on how to submit a progress report.

The HREC will then consider the continuation of the project for a further year (if necessary). Annually a number of projects may be selected randomly for an external audit.

**Provincial and City of Cape Town Approval**

Please note that for research at a primary or secondary healthcare facility, permission must still be obtained from the relevant authorities (Western Cape Department of Health and/or City Health) to conduct the research as stated in the protocol. Please consult the Western Cape Government website for access to the online Health Research Approval Process, see: <https://www.westerncape.gov.za/general-publication/health-research-approval-process>. Research that will be conducted at any tertiary academic institution requires approval from the relevant hospital manager. Ethics approval is required BEFORE approval can be obtained from these health authorities.

We wish you the best as you conduct your research.

For standard HREC forms and instructions, please visit: [Forms and Instructions](#) on our HREC website <https://applyethics.sun.ac.za/Project/view/Index/7031>

If you have any questions or need further assistance, please contact the HREC office at 021 938 9677.

Yours sincerely,

Mrs. Ashleen Fortuin

Health Research Ethics Committee 1 (HREC1)

National Health Research Ethics Council (NHREC) Registration Number:

REC-130405-012 (HREC1)\*REC-230205-010 (HREC2)

Federal Wide Assurance Number: 00001372

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Office of Human Research Protections (OHRP) Institutional Review Board (IRB) Number:  
IRB0005240 (HREC1)•IRB0005239 (HREC2)

*The Health Research Ethics Committee (HREC) complies with the SA National Health Act No. 61 of 2003 as it pertains to health research. The HREC abides by the ethical norms and principles for research, established by the [World Medical Association \(2013\). Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects](#); the South African Department of Health (2006). [Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa \(2nd edition\)](#); as well as the Department of Health (2015). [Ethics in Health Research: Principles, Processes and Structures \(2nd edition\)](#).*

*The Health Research Ethics Committee reviews research involving human subjects conducted or supported by the Department of Health and Human Services, or other federal departments or agencies that apply the Federal Policy for the Protection of Human Subjects to such research (United States Code of Federal Regulations Title 45 Part 46); and/or clinical investigations regulated by the Food and Drug Administration (FDA) of the Department of Health and Human Services.*



Enquiries: Zonwabele Merile

Tel no: 083 378 1202

Email: [zonwabele.merile@echealth.gov.za](mailto:zonwabele.merile@echealth.gov.za)

Fax no: 043 642 1409

Date: 16 October 2018

**RE: Vaccine stock management procedures in primary health care settings.  
(EC\_201810\_009)**

Dear Ms Chinwe Juliana Iwu

Dr Ntombenhle Judith Ngcobo

Professor Charles S. Wiysonge

The department would like to inform you that your application for the abovementioned research topic has been approved based on the following conditions:

1. During your study, you will follow the submitted amended protocol with ethical approval and can only deviate from it after having a written approval from the Department of Health in writing.
2. You are advised to ensure, observe and respect the rights and culture of your research participants and maintain confidentiality of their identities and shall remove or not collect any information which can be used to link the participants.
3. The Department of Health expects you to provide a progress update on your study every 3 months (from date you received this letter) in writing.
4. At the end of your study, you will be expected to send a full written report with your findings and implementable recommendations to the Eastern Cape Health Research Committee secretariat. You may also be invited to the department to come and present your research findings with your implementable recommendations.
5. Your results on the Eastern Cape will not be presented anywhere unless you have shared them with the Department of Health as indicated above.

Your compliance in this regard will be highly appreciated.

SECRETARIAT: EASTERN CAPE HEALTH RESEARCH COMMITTEE



Province of the  
**EASTERN CAPE**  
HEALTH

OR TAMBO DISTRICT OFFICE • ROOM 46, 11<sup>TH</sup> FLOOR • EASTERN CAPE  
Corner Owen and Leeds Street • BOTHA SIGCAU • REPUBLIC OF SOUTH AFRICA  
Tel.: +27 (0)47 502 9087 • Fax: +27 (0)465635910 • Website: [www.ecdph.gov.za](http://www.ecdph.gov.za)

Enquiries: Mr. T.D. Siyangaphi

Date: 18 OCTOBER 2018

To:	ALL SUB DISTRICT MANAGERS
From:	DISTRICT MANAGER
Subject:	Vaccine stock management procedures in primary health care settings

Dear Sub District Managers

This communication serves to inform you that Ms Chinwe Juliana Iwu Dr Ntombenhle Judith Ngcobo Professor Charles S. Wiysonge have been approved to conduct research study on "Vaccine stock management procedures in primary health care settings ". The three Researchers will be conducting their study in all PHC facilities in OR Tambo.

The National Department of Health together with SAMRC and University of Stellenbosch approved that the above study to be conducted in all PHC facilities in OR Tambo. The approval was again granted by the Department of Health Head Office after they have evaluated the research topic which was also approved by the Ethics committee at SAMRC and University of Stellenbosch. Upon completion of this study results will be shared with you.

Therefore, you are requested to assist them and for more information please contact District Manager's Office.

Yours in Health Services

  
MRS N.S. NTSHANGA  
DISTRICT MANAGER

DATE

18/10/2018

Cc: Ms Chinwe Juliana Iwu  
Dr Ntombenhle Judith Ngcobo  
Professor Charles S. Wiysonge

## Appendix 5: Search strategy for scoping review of interventions for vaccine stock management

### Database: Pubmed

No	Query
#1	Search "Vaccine management" OR "Vaccine stock management"
#2	Search "drug storage" AND (vaccine OR vaccines)
#3	Search "vaccine stockout" OR "Vaccines stockout"
#4	Search (vaccine OR vaccines) AND "supply chain management"
#5	Search (vaccine OR vaccines) AND "supply and distribution"
#6	Search #1 OR #2 OR #3 OR #4 OR #5

### Database: Embase

No	Query
#1	'vaccine management' OR 'vaccine stock management'
#2	('drug storage'/exp OR 'drug storage') AND ('vaccine'/exp OR vaccine OR 'vaccines'/exp OR vaccines)
#3	'vaccine stockout' OR 'vaccines stockout'
#4	('vaccine'/exp OR vaccine OR 'vaccines'/exp OR vaccines) AND ('supply chain management'/exp OR 'supply chain management')
#5	('vaccine'/exp OR vaccine OR 'vaccines'/exp OR vaccines) AND ('supply and distribution'/exp OR 'supply and distribution')
#6	#1 OR #2 OR #3 OR #5

**Appendix 6: Interview guide used for the study on mobile reporting of vaccine stock-levels in primary health care facilities in the Eastern Cape Province of South Africa: perceptions and experiences of health care workers**

1. Brief introduction of the participant
2. Knowledge of the SVS and how the system works
3. The effectiveness of the SVS in reducing occurrence of vaccine stock-outs
4. Any challenges with using the SVS?
5. If yes, what are the challenges?
6. What is most challenging amongst them?
7. Suggestions/recommendations for improvement